HIT Standards Committee
Final Transcript
January 12, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 21st meeting of the HIT Standards Committee. Again, this is a Federal Advisory Committee, which means there will be opportunity at the end of the call for the public to make comments, and a transcript will be available on the ONC Web site. A reminder for members to please identify yourselves when speaking. Also, since we have a number of members on the phone, if you could remember to mute your phone when you're not speaking and please don't put us on hold. So with that, we'll go around the table and introduce members who are here in the room, beginning on my left with Dr. Ondra.

Stephen Ondra – NeHC – Senior Policy Advisor
Hi, this is Steve Ondra from OSPC.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Anne Castro, Blue Cross and Blue Shield of South Carolina.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Walter Suarez with Kaiser Permanente.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Judy Murphy from Aurora Healthcare.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John Perlin, HCA.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, ONC.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Cris Ross – LabHub – CIO
Cris Ross from SureScripts.

Betty
Betty, Department of Veteran Affairs.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living, representing long-term….

Sharon Terry – Genetic Alliance – President & CEO
Sharon Terry, Genetic Alliance.

Marc Overhage – Regenstrief – Director
Marc Overhage, Regenstrief Institute and Indiana Health Information Exchange.

Judy Sparrow – Office of the National Coordinator – Executive Director
And co-chairs John Halamka, you're on the phone?

John Halamka – Harvard Medical School – Chief Information Officer
I am indeed. Good morning, everybody.

Judy Sparrow – Office of the National Coordinator – Executive Director
And also I believe we have Stan Huff on. Chris Chute, are you on the phone?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, this is Stan Huff.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Stan. Anybody else on the telephone, please?

Martin Harris – Cleveland Clinic – Chief Information Officer
Yes, Martin Harris, Cleveland Clinic.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Dr. Harris.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes, thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner.

Judy Sparrow – Office of the National Coordinator – Executive Director
David, thank you.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Judy Sparrow – Office of the National Coordinator – Executive Director
John.

Cita Furlani – NIST – Director
Cita Furlani, NIST.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Dixie, are you there?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I am. I was waiting for a chance. Dixie Baker.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anyone else?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker.

Judy Sparrow – Office of the National Coordinator – Executive Director

Jim, good morning.

Elizabeth Holland – CMS – Director, HIT Initiatives Group, Office E-Health Standards & Services
Elizabeth Holland for Karen Trudel at CMS.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Elizabeth. Anyone else?

Kamie Roberts – NIST – IT Lab Grant Program Manager
Kamie Roberts from NIST.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. And Kevin Hutchinson just joined us here in the room. I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good morning, everybody. Happy New Year to you. Thank you for your continuing participation. When you mentioned, Judy, that this is our 21st meeting, really, it gave us all pause.

I think the New Year is off to a rolling start. When one thinks back to the very beginning, the aspirations for progress and not just identifying a path but realizing a path to an electronic world that supports higher performance healthcare, it's just remarkable to see the progress. I mentioned that as one of today's activities is the report out from the hearings that the Implementation Workgroup held. I take away from that tremendous energy that is a reflection of the tremendous activity towards the ends that are being defined for meaningful use and the broader purposes of health information technology.

Before I go into a review of the agenda, approval of the minutes or any other introductory comments, I want to again thank the committee members, the public and ONC for truly remarkable work. And what at one sense feels like a one period of time, 21 meetings of the committee, but another is really short-order commensurate with the amount of work that's going on. And with that, it's my pleasure to introduce for introductory comments Dr. David Blumenthal, Department of Health, National Coordinator.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, John. Thanks for your leadership, all the John's, wherever they may be. I know from speaking to my wife in Boston there's a blizzard going on in Boston right now, so John Halamka, we understand your virtual presence. But I do thank those of you who do brave the elements to be here. We have probably a half inch of snow in Washington and that's usually enough to paralyze this city.

So, there has been an awful lot accomplished and all of it is founded on the work of this committee and the policy committee and the many workgroups and the inexhaustible, generous support that we've received from the community at large and the members of these committees in particular. Just a couple of points. Of course the meaningful use registration program went active January 3rd. The latest report was at the end of last week we had 4,000 registrants, which is a whole lot better than could have been the case.

Our standards and certification process, our certification process is going extremely well. We have five temporary certification bodies that have been approved. They've certified over 230 electronic health records and modules, and that number is going up almost daily. We have published our permanent certification regulation, so that certification bodies now can begin to plan for their application as permanent certifying bodies. We will need to do some work at the Austin National Coordinator through choosing an accrediting organization for certifying bodies. I will be working with NIST and the NAV Lab, the National Laboratory Certifying group to certify testing bodies.

In addition to that are many implementation programs are going full gun. We have, of course, 62 regional extension planners. I think by the end of this month they will have enrolled 40,000 primary care providers as interested in and committed to working with regional extension centers throughout the country to become meaningful users. We'll be releasing some encouraging information tomorrow at an event at

George Washington University on the progress and adoption with respect to primary care and the intent of the community to qualify for meaningful use, so stay tuned for that.

We also now have of course 56 states and territories with planning grants for health information exchange; 22 implementation grants have been approved and we're hoping that the remaining 34 will be approved by this spring. We have over 3,000 students enrolled in community college training programs that were created just last summer by the Austin National Coordinator at 84 community colleges and the multiple universities around the country. All of them have model curricula that was developed by the field with support from the Austin National Coordinator. And of course we have four research centers at work; one of them at the University of Texas has actually stood up a usability testing laboratory through which 18 vendors have voluntarily gone to get usability testing and feedback on their usability of their systems. So, it's an example of research being brought to bear on practice. And our regional extension centers are going to be closely following that testing process and trying to make it and its results widely available to their clients in the local communities around the country.

Of course that's all work that was put in process 18 months ago and we are already beginning and are underway with thinking about meaningful use stage II. We are in the middle of a 45 day comment period. It was initially 30 days, but we've extended it for 15 days at the request of the community on the matrix for stage II of meaningful use. And as we mature that matrix, we will be bringing it to this community to think about the implications for standards and certification criteria.

Yesterday there was a meeting at the NIH about imaging and the role of imaging as a meaningful use aspect raises a number of very important, interesting questions that I think we'll be looking at tackling. And undoubtedly if we move forward with an imaging component to meaningful use, the standards related to that will be important for this group to consider.

And we also as a very high priority for the coming year are thinking about interoperability. As you all know, in the rush to get the first version of meaningful use out and recognizing the state of capability for information exchange in the United States we put interoperability and high level more robust exchange somewhat in the back of the train. No reason to forget about it, but we realize that the field was not ready to engage in robust exchange. The report of PCAST reemphasized, and we'll be hearing more about PCAST later on in the morning's agenda, but it reemphasized the importance of exchange and the role of standards in ensuring exchange. And the ONC is thinking very hard about the set of tasks that we need to undertake in short order to make it possible for in stage II of meaningful use to have much more robust exchange information. And those go to standards and certification criteria, they go to privacy and security protection, they go to governance of exchange and the assurance that the public will need that conditions of trust and interoperability have been accomplished by organizations that are involved in exchanging health information.

So there's no much to do. So you all have had 21 meetings. If you're willing to keep coming to these meetings, we're willing to keep calling them and we do appreciate it greatly. I don't want to filibuster any more. There's enough filibustering going on in this city already, but I do again appreciate the John's leadership and I will let Jonathan now take over and let the proceedings go forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, David. Truly, from all us, thank you for your leadership and the ONC team. I think the pace, just to assure everybody, did not abate during what were entitled the holidays. I think everyone knows that ONC, in fact, does not really stand for the Office of National Coordinator, but the Office of No Christmas. Or at least that's what your staff say, David. We know that as well, but we appreciate the passion that everyone brings.

With that, we have an important agenda today and so many different convergent streams of activity. I look forward to really hearing more about the approach to the activities in this year as the comment period opens up for the stage II matrix, and the work that the standards committee supports that trajectory and the broader trajectory not only of the function of electronic health records in particular settings, the related health information technologies, but the interoperability of all of those functions. I appreciate the Farzad

Mostashari's leadership …wide as well as another thread, that which is the important message that really speaks very clearly, very directly to the importance of that interoperability, and that of course is in the message of the PCAST Report as well, so much work, so many threads of activity in the Office of National Coordinator. We'll then move to Ari Malec to hear more about the S&I Framework. Then we'll hear really about exchange and operation from a trifecta of leaders, Mick Tripathi, Walter Suarez and Jonah Frohlich talking about information exchange work group proceedings.

I would be remiss if I didn't at this juncture, and considering the next item on the agenda after lunch to miss thanking Judy Murphy and Liz Johnson for their leadership in the hearings of the past two days, hearings held by the implementation workgroup that I alluded to earlier that really I think speak also very clearly to the acceleration of activity, the excitement and the complexities of implementation across a variety of environments. I think we will have a lot of work to do hearing their report and really with the Office of National Coordinator contemplating the message and helping to, in a reflective way, think about how fast that helps to guide the charge of our work group and our support of the overall objectives.

Following that, Jamie Ferguson and I appreciate the continued activity of the Clinical Operations Workgroup. That interoperability includes devices, and devices are so important because they transcend so many of the environments that may more stereotypically come to mind really speaks to a continuity across traditional environments of health care, but also the patient contacts, patient home, etc.

As David spoke to, all of this rests on really a trusted fabric that allows things to go forward, and Dixie Baker and the Privacy & Security Workgroup have done such terrific work in helping to guide us.

Before we go to approval of the minutes, let me turn to my co-chair who joins us from icy Massachusetts. Actually, John, before we do, I noticed that we've been joined here by Jodi Daniel, from the Office of National Coordinator; Janet Corrigan from the National Quality Forum. Is there anyone else who's joined online? I want to make sure we recognize your presence?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
This is Carol Diamond. I'm online.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Carol.

Okay, let me just ask, since we have a large virtual presence today given the difficulties with weather and travel, as people speak, I want to make sure that all voices are heard, but all voices are identified. So if you would be kind enough to state your name before speaking or entering the queue, that would be helpful to everybody. With that, let me turn to John Halamka for any introductory comments.

John Halamka – Harvard Medical School – Chief Information Officer
Good morning, everybody. Thank you. We have had two power failures already this morning, so John Perlin, I do have an emergent wired phone downstairs that I'll run to should power cease for the rest of the day. It's all about backup and redundancy here.

So a few thoughts, as folks know, the way I always think about our work is content standards, vocabulary standards and transport standards. Now today's agenda is perfectly aligned, I think, with the further discussion of those three areas, because on the content side we're very good on stage I of meaningful use, but as folks go through implementation, I think they're discovering that there are areas of polish that could be even better. I'm in the middle of going through the hospital certification of Beth Israel Deaconess Medical Center and I can tell you the rigor of the certification process and the demonstration of content standards has required a substantial body of work. And as I go through NIST validation, I mean it's very clear that we want to make this as easy to implement for everyone as possible and, therefore, good implementation guides that are as complete as possible without ambiguity is important. So I think we'll hear today two aspects of content standards on the agenda via S&I Framework update where there are going to be three projects highlighted to enhance transitions of care documentation, to clean up some aspects of the clinical document architecture standards and implementation guides that

have been put forward by multiple organizations, and to ensure our HL-7 streams are as unambiguous and easy to implement as possible. So that's a very good body of work to talk about to make implementation easier.

We'll also hear more about the PCAST Report and a few folks on this committee are on that PCAST workgroup. I posted a blog yesterday to provide a backgrounder on some of the aspect of metadata XML and associated standards that that group will begin thinking about as we reflect on content standards and data elements that may be separable from document standards. So a very good agenda on content.

On vocabulary, there are several aspects of vocabulary, including as John just mentioned, vocabularies around devices. And of course we have had a rich body of work through the Vocabulary Workgroup on putting forth the notion of a centralized vocabulary repository where it would be easy for implementation to go to a central location for all the data sets, for all the various code sets and vocabularies one needs. And hopefully we'll hear from the Implementation Workgroups some feedback on both content and vocabulary.

And then on transport we'll, of course, hear the update on Direct, and to me transport requires a few things. It requires a trust fabric, so we will be talking about the notion of Dixie's group on privacy and security taking on certificate management processes and standards, and that's per the policy committee's request that we received in December. And we'll also reflect on provider directories, because if we're going to get data securely from point A to point B, we really need to know what way to transport it, where to transport it and ensure the security of its transport. So our agenda today reflects on all these aspects of transport.

I especially do, as John said, look forward to hearing from Judy and Liz on some of the lessons learned. Because as we think of our work for stage II and III, we want to make sure we are making it as easy as possible, reducing barriers and adding accelerators wherever we can.

So look forward to the meeting. And for whatever reason I cut out, Jonathon, it will be just minutes till I run to that wired phone.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, John. I appreciate it. I'm sure, knowing you, you have three or four backup. So we trust the continuity throughout the day. We thank you for those comments.

Let me turn to the administrative piece of business. I trust people have had an opportunity to review the minutes. I again appreciate the very thoughtful presentation of the minutes, the Office of National Coordinator. Please let me know if you have any corrections or amendments. I'm hearing none, so we'll consent that those are approved and move on to the order of the day.

It's my pleasure to now introduce the Deputy Coordinator of ONC, Farzad Mostashari, to begin with an overview and priorities for the Health IT Standards Committee in, hard to say, 2011. Farzad.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Good morning. Thanks for inviting me to speak about what our programmatic and policy priorities for 2011 are going to be and to engage in a discussion with you about what the implications of those might be for the work of the Health IT Standards Committee in the year to come.

Dr. Blumenthal mentioned some of the accomplishments of 2010 for the president's health IT agenda and they were significant, and we thank you for the really critical role you played into those accomplishments, both from the policy and standards perspectives, the design of, in many cases, the very design of how we approach certification and standards and meaningful use, and also the supporting structures that we established for the infrastructure for interoperability and adoption and meaningful use. We had what we hope will be an annual grantee conference at the end of last year and it was a remarkable experience seeing what had just a year previously simply not existed. We had extension center programs from every part of the country, health information exchange grantees and Beacon communities and workforce

programs and chart grantees all creating really a sense of community and shared mission around our goals of improving health and healthcare through better information and better technology. It was a remarkable moment, but also humbling in terms of the challenges that remain as we move from planning, which is a great place to be because you get credit for all the things we haven't done yet, to implementation in the earliest stages, which is a difficult place to be because you get blamed for all the things you haven't done and all the ways in which you're learning how to do what has never been done before, which is where we are today. But we think that we have, with your help, the right strategy, the right partnerships, the right programs and the right people, most importantly, to make progress on this agenda in the upcoming year.

Let me talk a little bit about where we see the priorities. Having put the big pieces in place, what are the priorities as we look ahead at 2011 and the challenges there? And then I hope as I discuss each of these you'll be thinking what does this mean for the Standards Committee and we can have a discussion about that.

The first, obviously, is meaningful use and registration is open for meaningful use and there are really an impressive number of eligible professionals and hospitals who are intending to achieve meaningful use in stage I in 2011 and 2012. We must do everything we can to help them succeed. This is really the …of the regional extension centers, but they're also important enablers in the ecosystem that have to change in order for the successful achievement of meaningful use, particularly around interoperability. When we're talking about laboratories, making sure that laboratories are providing information, structured information in an electronic format to those who intend to become meaningful users; when we're talking about electronic prescribing and the ecosystem, encouraging an ecosystem where pharmacies are participating in electronic exchange; public health, importantly, working with the CDC in states and local public health officials to ensure that they can participate fully and benefit fully from standards-based information exchange that is motivated by meaningful use; consumers to be able to receive their own health information and providers to be able to send information, patient care summaries to each other for referrals and transitions of care. Those are all meaningful use actions that require someone on the other end to also hold up their end of the bargain and we need to make that as seamless, as easy, as low cost as possible.

We also have to move forward on meaningful use and certification standards and criteria for stage II. And I think as we have discussed in the previous final rule, our intentions are to significantly increase the requirements around exchange and interoperability in particular, and pay renewed and vigorous attention to what we can do to improve security of health information through certification and standards.

Let's talk next about exchange and where we're going with exchange. As David mentioned, there is a cluster of interrelated issues, like a three dimensional puzzle, that have to fit together around privacy and security and the trust framework, standards and interoperability, governance, and an architecture for information exchange. In 2010, we tackled this complicated cluster of issues; the first for simple exchange. And I think we made significant progress on enabling directed exchange, both in terms of the policies, in terms of the protocols, in terms of the structures that we needed to support that. And I think the work to support that must continue in 2011, but we hope to really push that to the next level. Whether it's around having the directories that would support such exchange, whether it's around the certificates, whether it's around the operational aspects and the governance issues for intermediaries and the policy issues that still need to be formalized.

Yet, as Dr. Blumenthal mentioned, we cannot be content with directive messaging. I think the PCAST Report really highlighted and crystallized the promise and the challenges of creating a system, a true nationwide system that can support the more complex use cases for learning healthcare system, for queries, and we need to make real progress – and we will – make real progress in 2011. Those cluster issues, again, privacy and security policies, standards interoperability needed to support those policies, governance and architecture all at the same time in a comprehensive way.

We also I think on exchange have a commitment to enabling consumer mediated information exchange, where if consumers choose to be, they can be the medium for their own information exchange. And that,

I think, requires, importantly, making progress on an issue that has had an impending sense of we're almost there, but never quite reached it around identity assurance in a scalable way for members of the public. And I hope that in 2011 will be the year when we finally cross an important divide in terms of making that possible and connecting health sector to the commercial sectors and the progress that's being made there around scalable identity assurance.

Next on adoption, Dr. Blumenthal mentioned we'll hear news, encouraging news tomorrow about the increase in adoption of electronic health records in anticipation, I think, in terms of reflecting the momentum around Health IT. But we must do more, particularly around usability of the system. And that, I think, will be an important challenge for us, bringing transparency to usability, initially having objective systems for measuring usability and systems for operationalizing that measurement and transparency of usability in helping vendors have objective benchmarks by which to improve usability of their product.

We also, related to that, have to make progress on monitoring and intervening on adverse events associated with health information technology, while recognizing that on the whole we are much, much better off in terms of safety with electronic health records than without them.

On adoption we also need to be mindful as we enter a new phase of adoption to monitor and consider all of our policy options for intervening should a digital divide emerge around disparities in adoption and meaningful use of health information technology.

Third, we must reemphasize, resharpen the focus on healthcare outcomes associated with health information technology. The "what's it for," "what's this all for" part of our North star, which is improving health and healthcare. I think we all believe that as the provisions of the Affordable Care Act are being laid down in regulation and in practice, it becomes ever more important for us to link health IT to health IT enabled quality improvements, improvements in cost and efficiency, improvements in quality and safety, improvements in care coordination in the service of the transformed healthcare system. And to demonstrate the potential and the reality of improvements in patient safety and lives saved through the use of health information technology, not only at the organization and institution level, but at the community level, as we're hoping and believing we will learn how to do through the Beacon communities.

This, I think, implies focus on decision support, a renewed emphasis on decision report; moving it outside of a rarified environment of a few benchmark institutions into the broad, messy, somewhat chaotic ocean of real life healthcare. And really learning and improving incredibly rapidly how decision report is implemented and effectively used. We all know that decision support is, if inexpertly applied, can lead to alert fatigue, can lead to dissatisfaction just as much as appropriately implemented can lead to dramatic improvements in quality and safety. So taking from the laboratory, as it were, into daily practice is one of the great national experiments in health information technology that is happening, and we must do everything in our power to make sure that that transition is as successful as it can be.

The implications for health IT enabled transformation and health reform and delivery system reform are also particularly critical around quality measurements. We need to make progress on the next generation of quality measures now. We've taken important steps to set the priorities and the baselines and the infrastructure for doing that. 2011 will be the year, I hope, where we will really break through in terms of a generation of quality measures that are no longer kind of warmed over, claims based measures retooled, but actually measures that matter that use the full strength of health information technology, are outcomes based, are broad based and parsimonious and can be broadly used. Not only for meaningful use, but for many other quality measurements and delivery system reform activities.

Associated with patient safety is also the critical issue of medication safety and medication reconciliation. I think that's probably another priority where we need to move from what's possible to what is, as Don Berwick said, making the best of what we know the default of how healthcare happens.

Finally, as we have looked at our strategic plan, there are two other areas where we have, I think in 2011 our emphasis was really on the nuts and bolts, as it should be, as it was required to be, on the nuts and bolts of this enormous lift of implementing meaningful use and exchange and the focus on physician and

hospital care. I think as we look towards the future, we have to broaden the prism and take as proactive and accelerated approach to consumer e-health as we have done for clinical information systems. That means …forward progress on patient access to their own health information and all of what flows from that. Patients can get copies of their own electronic health records. Now what? How can we foster innovation in the use of that information to improve health for those Americans and how can we facilitate to the extent possible the use of that information across a range of applications.

We also have to pay attention to patient provider communications and the linkage between the consumer and the clinical information systems. And we have to, this came up in the quality measurement domain, we have to find practicable solutions for incorporating patient observations into clinical care and clinical information systems, both for quality measurement and for quality of care.

The other area where we have set the infrastructure but now 2011 is ripe for us to begin to set the table is around using the information that is mobilized for clinical care for the purposes of creating a learning health care system, population health. And importantly in this domain, enabling privacy protective methods of achieving our population health goals, including, importantly, standards, policies and architectures for distributed queries, distributed population queries in federated data models.

So, that was a lot. I'm sure we're not going to achieve everything we want to achieve in this year, but we will do our darndest and we ask for your help in the Standards Committee and for those on the phone as part of the larger health IT community, your help in helping us with the design and the strategy, but also with the real world implementation of these important challenges. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Farzad. What shall we do next?

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
I would love the conversation.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It is a very ambitious agenda, but it's very exciting, because I think what you outlined are all of the clinicians holding interstitium between much of the work that's going on that makes that learning health system, that connectivity possible but advances healthcare.

Let me turn to Dr. David Blumenthal and then we'll engage with the committee for discussion.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well first I want to thank Farzad not only for that presentation but for the enormous contribution he makes every day at ONC; terrific asset to our agenda.

There's a very long list of things we have to do and part of our job is to decide which are the make or break requirements. Every one of the things that Farzad mentioned is important, but I think that in some ways the next peak, I think the metaphor that we're increasingly using at ONC, aside from the absence of Christmas, is a mountain climbing metaphor. And it seems that every time we get to a peak and just peak over the peak, we see an endless vista of new mountains that we have to climb. But we have to pick the next mountain and I think the next mountain in many ways is interoperability and everything that surrounds it.

In part I think we feel a sense of urgency, because we fear that if we don't lay the groundwork for that soon that we may not be able to do it later on. And that means having a robust policy around privacy and security, and we have a tiger team working on that; it means having the standards in place that will assure that willing providers can technically exchange information if they wish to; it means having the community and national resources, organizations, rules, regulations, systems of governance in place that enable us to solve problems when they inevitably arise. If we can do that over the next year, I think we will have accomplished an enormous amount. Not to say that we can ignore all the other important things that we have to do, we have to get to stage II of meaningful use right and we have to get the certification

of records right for stage II of meaningful use, which means we need manageable criteria, we need test instruments, we need all those things, but I think the thing that's going to sort of flow to the top of our agenda in the next period of time is going to be interoperability, and all the things that are attendant to it. There's a long list of things that are attendant to it.

So, that's just a little bit of navigational information. Having said that, we would welcome comments and questions from members of the Standards Committee.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I saw, Cris and Mark, did you want to weigh in?

Cris Ross – LabHub – CIO
Actually, David answered my question, as he usually does, before I ask it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Liz Johnson.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
This is Liz Johnson. I just want to reinforce what Dr. Blumenthal just said. We just sat through a day and a half of hearings and we consistently and with every panel heard please get us information on interoperability. We want to do it, we think it's the right thing to do, we need guidance. So I think you're dead on.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other thoughts? Anyone online?

John Halamka – Harvard Medical School – Chief Information Officer
I absolutely share David's statement. If we have 50 HIE's or 56, whatever the right number of sub entities is, all working on mechanisms of exchanging data in their local clinical service areas, we're going to end up with 56 different provider directory formats, 56 different transport formats and a set of security arrangements that work wonderfully locally but may not allow transmission across the state line. And so if we can just get folks provider directories, the certificate and trust fabric and the transport they need, I think they'll all be happy to implement it in one way. As Liz has just said, at the moment they don't have that singular guidance, so this is the year.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. John Derr.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
I just wanted to emphasize that we are working on interoperability and long-term post acute care. We're getting into a lot of the health information exchanges with nursing homes and home care. We've just published a large document to put on the HIE Website for getting behavioral and also long-term care into interoperability, and we're working on the quality measures at the same time because that's very important to us.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great comment. Others online? Judy Murphy.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Just to put a little more meat on those bones based on what we heard yesterday, specifically related to HIE's, there actually appears to be a bit of confusion between the new state designated entities and the existing HIE's in different areas. What we heard, actually, were the private ones or the more local ones were the ones that were more successful and the newer ones are the ones that are struggling a bit. Don't know if there were issues with funding, there was some question about the funding not coming as quick so they couldn't hire all the people, but I think specifically we were hearing that there's confusion. In other words, if people want to participate in HIE's, they're not exactly sure who they should be

connecting with. Then at the standards level we heard loud and clear in several different areas, "Just tell us what to do. Don't give us options, just give us this is the standard." And again, comment that John Halamka made is spot on there. We have to be more directive, I think, in that specific space.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Judy. Dr. Steve Ondra.

Stephen Ondra – NeHC – Senior Policy Advisor
…comments, there's a couple of important themes. One of the things is what should be common? But as we think about the things that should be common and directed, we often tend to think of it from a specific perspective – direct, exchange, consumer aggregated. I think it's very important that we consider what are the common things that should be directed to support the entire ecosystem of interoperability rather than any particular part of that. Because each of those pieces of interoperability, each of those different approaches serve a different business use case, a different need in the community. So I think it's very important that we consider those things that are directive and common from the perspective of all the pieces that form the ecosystem rather than any one piece.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think there's a very consistent theme that's emerged and really reflecting on what John's point was and Liz's, is that if each use case has driven a particular approach to Farzad's comments in terms of outlining our work ahead, interoperability, governance, architecture, etc., then we end up with a cacophony. And so extracting the most common use case that allows the maximal interoperability with early clarity so that folks in the midst of adoption can move its very important.

David, I think your metaphor of the field of mountains is so important, but you also made very clear that to scale the next peak there are a number of tendencies. That's really one of the themes I heard in Farzad's comments as well is that it's difficult to just aggregate, as tempting to my feat to say we're going to do A and then we're going to do B, gets very difficult. And I think Dr. Ondra's point here is that you do A and B and C in isolation, then you end up with disparity that doesn't yield the end good. The other is, is that if people are working at this in real time, the earlier message that the better. So it is ambitious and urgent for all the right reason. And in point of fact that urgency is actually more feasible than trying to disaggregate. So, I think we heard that message.

Linda Fischetti – VHA – Chief Health Informatics Officer
Just to point out something that I'm sure everybody in the room caught, but we keep using the denominator of 56 as the total number of solutions that could possibly pop up in front of us, and then we heard about one discipline of rehab and long-term care. I need to leave early today because I'm going to a substance abuse center health meeting, which is now looking at how they can use the HIE's to drive their quality and outcome. So I think it's really 56+n, which is all of the other unique communities that do have specific interoperability needs.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I heard someone trying to weigh in online.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. David, in a prior meeting you made a comment about walled gardens of interoperability and I wasn't able to listen to the implementation meeting yesterday, but what I heard was a sense of private exchanges that are not open exchanges being more productive and a recognition that often hasn't occurred that's participating in an exchange as a hospital is not free. It takes substantial resources from projects that might be doing other things to obtain meaningful use or implementing new instruments to the nursing unit or whatever. And we have this, on the one hand we have this notion of accountable care organizations, which seems to imply the first real higher incentive and return on investment for having interoperability that may have ever seen. And how are we going to deal with the difference between that incentive and motivated interoperability and the broader need for interoperability across the country for patients that move in and out of the accountable care organizations or are in…organizations at all or for research and public health and other use cases that tend not to be as well funded?

David Blumenthal – Department of HHS – National Coordinator for Health IT
So I understand the question, Wes, you're saying there's a conflict between the tendency for exchange to occur spontaneously and within narrow confines, organizational confines, economically motivated jurisdictions and the need to create more robust, broader exchange.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. Fundamentally, interoperability occurs more easily when there is an economic incentive to do it. And I don't mean incentive in the sense of a period of bonus payments from the government. I mean we can do business better, we can pay money, we can take more money, we can keep our mission alive as a non-profit longer if we do this interoperability. And the investment is not solved in participants in an exchange, so this is an issue that often goes to the board.

The question is, how do we challenge that kind of very focused exchange against the broader needs for exchange in the country?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well, the issue of exchange for what purpose and rewarded how is pervasive. One, we have a series of mechanisms that try to overcome parochialism and sub optimization, if you will. One is the meaningful use framework. And as we work on meaningful use stage II and stage III, we have messaged and will continue to message and continue to try to include criteria for meaningful us that will require robust exchange as a qualifying criteria. So you all will have a chance to see what the meaningful use framework comes up with. And even if we don't get it exactly in stage II, I do hope that the message will go out clearly that stage III will have even a higher criterion associated with it.

Now that's going to have to be reduced to practical applications. So what does it concretely mean when we say "robust exchange"? What are we going to require of hospitals? What are we going to acquire of eligible providers and how are we going to measure it? And what numerical, what's the numerator and what's the denominator? So that's point number one.

Point number two is that the department is writing regulations right now for what constitutes an accountable care organization. And those regulations have the opportunity to speak to exchange. I can't tell you what's going to be in the regulations, but I can tell you that the issue of information sharing is under discussion. I also think that if we get the incentives right, we won't have to fight this battle very long because Jamie Ferguson is sitting here to my left and I can't think of any organization that better embodies an accountable cure organization than Kaiser Permanente. If the expenses are internalized, the care is internalized, yet Kaiser is a very, very strong advocate of interoperability and exchange. Why is that? Because they are accountable for the cost of the care of their patients and their patients use other providers. And they need to know about it and factor that in, that they use providers who are not members of their organization. They go to the VA and the VA, they want to know what's happening at the VA.

I think the successful accountable cure organizations are going to learn that they really have responsibility for the cost of the care of the people that they sign up, they're going to have to work with other providers in their community. And in terms of getting information to flow across communities, across states, across large geographic areas, except for a very small number of organizations like the Mayo Clinic or the Cleveland Clinic or organizations that have huge referral bases, that's always, I think, going to be driven at much, that kind of exchange is always going to be driven as much by professional incentives and special relationships as it is by economic motivations. But we have to create the basis for that, technically. It's going to be a different business case than what happens locally among accountable care organizations.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. I think we are seeing the emergence of a new economy. I want to be mindful of time, so let's take the four last comments. Before I do, I've been remiss in my duties by not acknowledging Doug Fridsma who's been the line since the beginning of the call. So we'll close this discussion with four

comments going around the room here, starting with Sharon Terry and going to Kevin Hutchinson, Cris Ross and then to Walter Suarez.

Sharon Terry – Genetic Alliance – President & CEO
Thanks very much and this is very exciting to hear this phase of ONC's strategic planning. We're very interested, of course, in the consumer issue than the interstitial space there around interoperability. In some ways it's less complex and in some ways very much more complex. And I am reminded of mountain climbing, that when you get to what you think is the peak, there is another peak level and all the peaks around there.

And specifically interested in things like how we do the kind of privacy and security protections we need as well as continue to do the exchanges with newborn screening blood spots, with screening throughout the lifespan, medical home integration, those sorts of things I think will be really rich places for use case scenarios that we've begun to build. Now, we need to look how standards affect something as simple as, I'm working right now with Orphan Met in France with the NLM in the U.S. around nomenclature for rare diseases, looking at the ICD-11 codes that we're working on and maybe just trying to harmonize those kinds of things, really rich spaces that are complex.

So I think this will be a really fun year to look forward to and I look forward to the challenge, really thrilled by the work that you're doing.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Kevin Hutchinson.

Kevin Hutchinson – Prematics, Inc. – CEO
This is more of a comment. I'm going to take Wes' role while he's out of town. Sorry, Wes. But it's an important one because I hear it all the time, particularly as we look at the priorities for 2011 and Farzad is bringing on the … I think back when we first built SureScripts out and we knew the first four to five years we wouldn't make any money, because the price point you have to offer these services at is going to have to be at such a low price, the only way you'd make money is volume. And we see a lot of the smaller information exchanges and interoperabilities that there probably is going to be mergers, rollups, organizations are going to grow, expand, product lines have to expand. You can't find one business model and say that's who we're going to charge, that's how we're going to make money. It has to be spread across multiple organizations and the value price has to be set accordingly.

One of the things that I'm starting to see happen on the entrepreneurship side that we really need to figure out how to get a solution to is around private industry investment in this space. There is a large concern by those that could fund innovative organizations that could bring innovative solutions to the market about the role of government in the area of interoperability, both from a positive standpoint as well as a negative standpoint. Because the positive is there's organization happening, there's decisions being made, there's requirements going to be had around interoperability and this is all a good thing. We don't yet know who's going to pay for what from a private industry sector, but lots of buzz, JP conferences going on, JP Morgan conferences going on, lots of things going on where people are very excited about this space. But then you start sitting down and having very serious conversations in a particular space, particularly around interoperability on the topic revenue today and there's this "what if?" "If the government builds out the National Health Information Network, if they operate it, they're going to control it. If there's…" And we see this wait and see – maybe we should pull back a little bit, wait and see what's going to happen in 2011 before we make that investment in this space.

And maybe this is more of a policy committee decision than a standards committee decision and more of an ONC topic than this committee's topic, but I felt it needed to be brought up, because there's money, investment money waiting to be had to put into this space of interoperability. But at the same time, there needs to be, and I know this is hard to do, a stake in the ground, some kind of more clarity, less gray as to the role of the private sector, the role of the government sector in the area of interoperability before we see those checks starting to be actually cut. Lots of ideas, great PowerPoint slides, wonderful meetings that are being had; lots of money sitting there waiting to be poured into this space, but lots of

nervousness with respect to the role of the private sector and the government sector. If we could get clarity to that, there's all kinds of things that would be released in 2011.

David Blumenthal – Department of HHS – National Coordinator for Health IT
The money's in the meeting planning industry right now.

Kevin Hutchinson – Prematics, Inc. – CEO
That's right. Exactly.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're aware of that. I don't know what level of certainty and what issues is required, but we are trying to, I think a lot of this has to do with governance and how governance is defined. We are required to write a regulation on that and we will be doing that over the next six months, six to nine months. These things don't happen fast and it's very complicated. We do feel both that we want to make a lot of room for private sector innovation, but we feel also that there's a central foundation for consumer protection that we have to provide to make sure that consumers information is used in a way that they are comfortable with. Those are the two things we have to balance.

I think it's in the interest of industry to know that the public trusts the interoperability framework. Because if they don't, it will ultimately fragment and the opportunity they sense won't materialize. So we have to all work together to find that sweet spot.

Kevin Hutchinson – Prematics, Inc. – CEO
This is a followup to that and Stephen's comment. If we look at the overall ecosystem of this world of interoperability, there's two basic categories – and I mean basic categories: content, patient information moving around to help decision-making versus business transactions like lab orders and prescription orders and referrals, things that actually drive revenue. And at the beginning of these discussions around businesses that can be built, create an expanded fund, merge, rolled up, other things, it focuses on those things. How is an organization going to make money in facilitating the improvement of healthcare? And when you think about it as one content, moving patient information to help decision-making as one thing, but actually driving core businesses that drive their orders, their revenue, claims transactions drives revenue, it's payment, requirements for that, moving medication history information around is valuable because it helps in decision-making. I wouldn't necessarily say it drives revenue, but it helps in decision-making. You might charge a subscription fee for certain things like that and there could be a small business model there, but it has to be part of that. We need to think about that from a content perspective versus a core orders perspective that drives business.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. Terrific interchange and it takes us back to the very beginning and the sweet spot necessary…clarity for directionality and also the space renovation. That we're having this discussion at this point I think also gives credence to the progress as well as the opportunity of that merging …

Let's take a couple of comments from Cris Ross and Walter Suarez and we'll close this particular segment. Cris.

Cris Ross – LabHub – CIO
I'll try and be concise. Farzad, when I listened to everything that you say that should be the focus for 2011, it all makes sense. It seems like the right order and emphasis. So the question is always well what aren't we doing that wasn't listed? I would say that based on what we heard from the implementation hearings yesterday, I think there's a need to have internal process improvement around what we're doing. We didn't hear people say that there was anything wrong-headed or wrong directioned around meaningful use. The comments that we got were about its application and its implementation, and they were reasonable, helpful, constructive kinds of comments. And I think that would be helpful to integrate in part of this process; how can we do better at stage II than we did at stage I?

Then I think one particular issue that's relevant to our committee and maybe the Policy Committee, is if I were to think about places where I wish we could have done a better job in the last year and a half, it would have been better alignment between standards and policy. I think sometimes standards got a head of policy; sometimes the policy wasn't fully articulated before we began our work, and so on. I know in the minutes of our last discussion around the topics just coming up – PCAST and S&I – there was discussion even then around, well, wait a second, where's the policy that's going to help guide the standards development? So I think it's still a really relevant issue and I hope our committees can focus on that and I would urge ONC to take the feedback from the Implementation Workgroup around internal process improvement as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. I think that's also a fair charge back on the committee that we should be sort of self-improving through the process then in the context of some of the guidance that return. Thank you. Farzad, did you want to comment or we'll move on. Okay, Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Okay. Well, this comment comes out of some of the things that I heard already and particularly yesterday's and Monday's hearing on implementation. I think the fundamental reason why we do exchanges, whether it's within or across organizations, is for care coordination. Continuity of care and care coordination are the fundamental reasons why we send an order to a lab or we request a referral to a specialist, and I think we're running a little bit the risk of creating silo reporting of meaningful use metrics for organizations. So each of our organizations can say, "We're doing great within our population." So my thought is really we need to begin to look at opportunities, perhaps meaningful use II and perhaps along the responsibilities of health information exchange organizations, to measure meaningful use of Health IT to improve community level health and community level health meaning not just healthcare by a particular organization within its numerators and denominators, but looking at how we can incorporate measures that ultimately measure the improvement of a community at large by virtue of the option of health IT.

So, my thought, my encouragement would be to try to begin to look in that direction as well. I know we have some measures in stage I that look at some of that, but I think ultimately to avoid this conceptual creation of silos, improve reporting …organizations and meaningful use, we've got to begin larger than just organization-based reporting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Walter. Let's close this session. John Halamka, anything you'd like to offer before we come to Farzad for any last words on this?

John Halamka – Harvard Medical School – Chief Information Officer
Just what I thought, and that is that Farzad and David have outlined a full plan of activities. We have 11 meetings left in 2011, and then of course we have our workgroup meetings that will be on an integral basis. What I hope that, Jonathan, you and I and ONC can work on before the next meeting is a work plan to lay out how February through December we will, at our meetings, address these issues in a timely fashion so that ONC has all the guidance it needs.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John, you can't see all the heads nodding in unison, but absolute concensus on that point. By the way, we received a picture from John Halamka from his living room window and …to say, when I flew over the North Pole a few weeks ago, I think I saw more grass poking out in Boston.

With that, let me thank everyone for the discussion. I think that's a terrific charge, a work plan, and it's sort of a summary of what we've done, but also the need for coordinated activity as we move forward with a very specific timeframe.

Let me turn back to Dr. Mostashari to offer either any final comments on this section, but also initiate discussion of the PCAST Report review. He has perhaps some introductory comments on the new

committee that's been formed to help provide and inform the forthcoming work of our group policy in ONC.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Judy, do we have the ability to put up the slides that were initially part of the IE? There are a few slides that I'll borrow on the PCAST process.

I'll be brief here. There was discussion, I believe last month, workgroup committee meeting about the PCAST and really my hope is that next month we will not only have the workgroup members and chairs be able to tell us about some of the preliminary findings, but will also have, as I'll explain, the opportunity for the Standards Committee as a whole to participate and hear a full day of briefings on the PCAST Report. So today I'll be brief and give you a brief update on what's happened since.

As you know, on December 8th the PCAST Report came out and we immediately published in the Federal Register a request for public comment towards a set of questions. Those are due, I think, are going to be closed down on January 17th. We created a workgroup to provide perspectives on that report.

The charge of the workgroup is really to help explain to the health IT community what the implications of the report might be for our health IT strategies and potentially programs. It is not to pass judgment, not asking one federal advisory committee to pass judgment on the recommendations of another federal advisory committee. We're really asking them to take a report that really came from a perspective that was not the traditional. I think this the strength of the report that takes what has been done and possibilities industry as a whole and in other realms of information exchange, and has applied them to the health IT world.

But there's a significant amount of work that remains to help us understand what those words really mean in the context of healthcare. What does universal exchange language mean in the context of what's already happened in health IT and what's the existing situation and what would be the implications and challenges towards implementing the next step towards the shared goals that we all have.

When we're talking about metadata, what has already been done, what would be the implications for taking it the next step forward – would that be done potentially incrementally versus in more of a transformative way? What would be the implications for data models and extraction layers, what would be the implications for query architecture? What would be the implications for privacy and security?

So we've asked this workgroup, which when we went around and people introduced themselves and what they've been working on, it was as impressive as any workgroup we have ever created and continually humbles us in terms of incredible individuals like yourselves who take the time out of your incredibly busy schedules to provide this public service, for which we're very thankful. I'll just run down the list of members of the PCAST Workgroup.

The chairs are Paul Egerman and vice chair Bill Stead. From Vanderbilt we have Dixie Baker from our very own Standards Committee, Hunt Blair, Tim Elwell from Misys Open Source, Carl Gunter, John Halamka, of course, Leslie Harris from Center for Democracy and Technology, Stan also is on the workgroup, Robert Kahn, Gary Marchionini, Steve Ondra, our very own. We have, again, John Perlin. The John's are in full force. Rich Platt from Harvard Medical School and the Sentinel Project. Wes, another stalwart. Mark Rothstein, Steve Staff from the American Medical Association and Eileen Twiggs from Planned Parenthood. Quite a roster. And the more we learn about people's experiences, the more confident we are that we will get not only a fresh perspective, but also a perspective that's firmly rooted in the full knowledge of the field and the potential implications.

We asked a series of questions in request for information that we hope staff will process, but we hope that the workgroup will really synthesize and extract from those comments the key indications and issues. We asked what standards implementation specifications, certification criteria processes for electronic health record technology would be required to implement the specific recommendations from the PCAST Report. For example, that ONC establish minimal standards for the metadata associated with tact data

elements and that ONC facilitate the rapid mapping of existing semantic taxonomies into tact data elements.

Second, what processes and approaches would facilitate the rapid development and use of these standards? Third, I think this is critical important, that given currently implemented information technology architectures and enterprises, what would be the challenges this industry will face with respect to transitioning to an approach such as what was discussed in the PCAST Report? And then what are some of the solutions or best practices that could be leveraged to expedite the transitions?

We asked what technological developments and policy actions would be acquired to assure the privacy and security of health data in a national infrastructure that embodies the PCAST vision? And how might a system of data element access services, DEAS, as described in the report be established? And what roles should the federal government assume in the oversight or governance of such a system?

Six, how might ONC best integrate the changes and vision by the PCAST Report into its work in preparation for stage II of meaningful use? Seven, what are the implications the PCAST Report on HIT programs and activities? Eight, are there lessons learned regarding metadata tagging in other industries that ONC should be aware of? And nine, are there lessons learned from initiatives to establish information sharing, languages, universal languages in other sectors?

So the workgroup is going to look at the report very carefully, dock it, as it were, to the language and understanding of what's happened in health IT and health IT standards of interoperability to date; review the comments that were received in response to the request for information. We're going to have a day and a half of briefings before the full committees in conjunction with the next February Standards Committee hearing. And we hope to have a preliminary report to the Standards Policy Committee in March and a final report in April. So again, a very accelerated timeframe, as usual, but we feel that to really understand the implications and options for our policies and programs it's urgent that we have this important report reviewed as quickly as possible.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Farzad. I think that's a terrific summary of the activities in place. We should probably take that as informational. I think everyone's had access to the report to review that. And to Cris Ross's good comment that we keep in synchrony, I think there is a convergence that's planned in. And whatever the discussion of metadata in the PCAST Report or meta tagging, the meta message is very symmetrical to the conversation we had here earlier about creating that ecosystem and driving it forward for really informed healthcare in the future.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
And also, I think you're absolutely right that it also harmonizes nicely, as it were, with the concepts that we need to consider. Not only the technology innovations, but also in inextricably linked and simultaneously optimized the privacy and security governance issues as well as the standards issues.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Appreciate that and appreciate you helping to really make sure that those threads converge with all the workgroups as appropriate and necessary to the timeline.

We have another ..that really begins to move from an articulate of what the next body of work is to actually working on that next set of activities. And we'll move here at this juncture to Directory Standards, a discussion of information exchange workgroup activities. Perhaps I'll turn to John Halamka to introduce this set of activities. We have Walter Suarez with us in the room, Micky Tripathi, Jonah Frohlich, I believe, are virtual today, but John, let me turn to you.

John Halamka – Harvard Medical School – Chief Information Officer
Question. Do you want to do the Direct Project…

Jonathan Perlin – Hospital Corporation of America – CMO & President

Apologize. I went right over that. Moving right along. Hold that thought. It may be time for glasses. Direct Project Update, S&I Framework and it's my pleasure to turn to Arien Malec for discussion. The introductory comments stay the same as we transition from what we'll do to actually working on the tasks at hand. So Arien, are you there?

Arien Malec – RelayHealth – VP, Product Management
I am here and I believe also that Doug is beaming in from tomorrow's very early morning, so he can chime in as well. I'm going to give a very brief update on the Direct Project and then spend most of the time on the launch of the S&I Framework that we did last Friday.

In terms of the Direct Project I think the major summary is that we greatly appreciated the feedback from the Standards Committee and from Dixie's Privacy & Security Workgroup. We have updated the specifications. There has been a tremendous amount of discussion particularly around some of the policy-oriented questions in terms of the expectations for a receiver of data and what kinds of data they need to receive from a policy perspective and how to distinguish that from the actual technology specification in terms of the specification itself.

So I think we've got to a good place in that discussion and we're in a place where we've got three documents that I think are going through the final stages in the Direct Project community review. There's the core specification for SMTT and …, now labeled the Applicability Statement for Secure Health Transport. There is a supplemental specification on how to use XDR and XDM in the context of direct messaging and a gateway mode. And then there's a really important document that we're working on that explains what, at least from the direct project's perspective, it means to be direct compliant and that's what we'll put in both the expectations on supporting the core specification, being that we'll send and receive modular trust from other people who've implemented the core specification where the XDR and XDM specification fits into that, and the expectations on receivers, particularly on receivers who are care providers, expectations on them to receive both structure and unstructured data and be able to receive from the widest set of exchange participants.

That package of three documents I believe will be through our concensus process in time for the next Standards Committee meeting, but as people who have been involved in such efforts understand, the pass of documents, the finalization sometimes is not completely linear. But I do believe we'll be there.

We're also eagerly awaiting our first production transaction in a production context. We have seven to eight implementation geographies, actually more that are in planning stage right now, and one of them is all hooked up, has gone through all of its implementation testing and is simply waiting for the provider to send the receiver, in this case immunization transaction. As soon as that happens, we'll have our first production transaction. We believe we'll be at two to three operational exchanges by the end of the month and likely in the three to five range by the end of next month.

So that's the quick update from the Direct Project. I'm going to turn now to the Standards & Interoperability Framework. Doug, I assume you're on as well.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I'm here.

Arien Malec – RelayHealth – VP, Product Management
Do you want to tag team on this? How do you want to handle it?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, I'm 16 hours into the future, so I'll try to give you as much heads up on what's coming.

Arien Malec – RelayHealth – VP, Product Management
Yes, Doug has a unique view into the future of health information exchange. The Standards & Interoperability Framework, we'll do a brief overview here in terms of what the framework is and then spend most of the time on the announced initiatives that were launched.

The framework as a whole, as I think Doug's explained to the Standards Committee multiple times, is a set of integrated functions, processes and tools to guide harmonized interoperability for healthcare. And it consists of a number of functions that are integrated through to create harmonized specification that are backed by robust models, informatics models that underlie those implementation specifications and the testing that goes behind them. And the reason for having an S&I framework isn't to model or apply informatics for informatics sake, it's that we recognize that when there are multiple specifications in the exchange of health information in support of meaningful use, in support of quality outcomes for accountable care organizations and the like, and supportive improved care, improved health and improved quality and cost reduction, we recognize that when we do work in one area we need to make sure that that work is harmonized and levered for the work that we do in other areas. So as a classic example, when we receive lab data in a lab report, we need to make sure that that lab data is immediately available for quality reporting and decision support, and making sure that those standards are harmonized is a crucial value in making sure that the whole cycle of quality improvements for information technology is there.

That being said, the intent is for each of the focus areas for interoperability take place in a mission-driven, value-driven way, focused on a specific interoperability challenge and focused on giving point guidance or explicit guidance to implementers to solve a particular problem. So the point in using a framework, a standards and interoperability framework is not to boil the ocean on interoperability, boil the ocean on standards, but to solve point problems in a context that allows for the solution of those point problems to be used in a wider context. So if we can go on to the next slide.

It's really critical, by the way, on that last slide, that there's a focus on value and outcomes throughout the S&I framework. That as we we're giving the guidance, or whereas we're setting the stage to give the guidance to implementers, that we do so in a way that's focused on value and outcomes. Where value and outcomes isn't defined as we've got a standard…process, but value and outcomes as defined by both utilization and then, more importantly, by the quality improvement this utilization drives.

In terms of the overall process for the S&I framework, I think it's really important to understand where the S&I framework fits in the broader ecosystem, both in the broader policymaking system as well as in the broader standards making ecosystem. So one way to read this diagram is left to right, and recognize that the context for the S&I framework is set by the Policy Committee in its role for recommending policies related to health information technology broadly and in defining the expectations for meaningful use specifically, or recommendations for meaningful use specifically. And then over on the right there is both a policymaking and a critical role for the Standards Committee in catching the output of the framework. So, the Standards Committee has a key role in articulating the standards and interoperability challenges that are facing this industry through the work of, for example, the Implementation Workgroup, the Privacy & Security Workgroup, in fact all of the reports out that are occurring at the end of today or at the remainder of this meeting. And then the Standards Committee, of course, has the key role that outlines in high tech to take proposed new standards and implementation specifications, certification criteria and the like and evaluate them to make recommendations to the Office of National Coordinator.

So the S&I Framework really fits in the middle of those functions as an aid to that process to make sure that we've got a disciplined process for taking interoperability challenges, working them through a process of harmonization and testing, and then handing them to the standards committee for evaluation or recommendation back to ONC for inclusion, for example, in certification criteria.

The other key policy coordination function you'll note, and it's a little hard to read in the …box, the ONC policy steering group, which has the critical function of taking the policy implications of technology, making sure that we understand them well, have vetted them appropriately, and that function has the responsibility of surfacing those issues to the Policy Committee for evaluation. We didn't do that really well in the Direct Project, in the first couple of months, but I actually think we hit our stride and came up with a reasonably good policy for taking the myriad of policy issues that we ran into in the technology development and then surfacing them appropriately. And the partnership between, for example, the tiger team and the Direct Project was pretty strong. Even though the tiger team quite appropriately never

worked on Direct Project's specific policies, all of the work of the tiger team was incredibly helpful in working through the Direct Project and we think that kind of partnership will be also needed and critically important in the S&I Framework.

So that's how the S&I framework fit in the overall policy area. And then in terms of where the S&I framework fits with regards to the standards development organization and the broader healthcare community, you can read that in the vertical access. The point of the S&I framework is not be a standards development organization. It is not to create new standards; rather, it is to identify and create, harmonize implementation specifications for particular context for healthcare. That needs to draw from and also feedback into the work of the standards development organization. We recognize that there are multiple high quality standards development organizations that serve healthcare, and that for the needs of national health priorities, including meaningful use, that those standards need to be harmonized among them in order to create a strong package and implementation specification.

And then on the top we need to serve and be informed by the broader healthcare community as well as by federal partners. And the participation of the community of users, the community of interest in the S&I framework process, both at the standards development organization level and at the practitioner and implementer level, at the top is incredibly critical. So we serve multiple masters in the S&I framework and our ability to do our job well is predicated on our ability to communicate with and communicate to and involve all of the other actors in the larger ecosystem.

Next slide. So as I mentioned, the way that we could work through the S&I framework is not to solve all problems through single, harmonized framework that then gets rolled out by magic, but to develop the integrated connected health information specification through specific health interoperability initiatives. That is to say, problem and value centric and outcome centric, and stay specific in the initiatives that we do while being mindful of the need to harmonize across those initiatives and drive that up to a larger vision for interoperability.

So each S&I initiative focuses on a single interoperability challenge and a single set of golden outcomes that tie to measurable value across the health information exchange, HIT, and healthcare broadly. And the output of that initiative or content specifications and then tools and services that are available for implementers to implement the technical specifications. And then each initiative relies on a call for participation of the broader community. We have a set of resources, of taxpayer funded resources that are assisting the S&I framework, but our ability to accomplish the mission, the broader mission is incredibly predicated on robust support from the larger community. We don't have the knowledge expertise to go alone. We need the participation of the standards development organization and the participation of several partners, and of course the much broader HIT community. So for each initiative we put together a call for participation and are doing all of our work in an open and transparent way through the wiki that you see there, wiki.siframework.org.

Next slide. As you know, the HIT Standards Committee published on the list of initial priorities. Or at least our initial take on priorities as well as on our prioritization framework. Out of that SOCA blog hosting we got 31 detailed comments from 21 representatives, and there were some broad themes on the prioritization framework, where we needed to simplify the prioritization framework; that weighting and scoring is oftentimes a black art and that we should be as transparent as possible; and that we need to include cost benefits, we needed to include the cost side as well as the benefit side, and make sure that we got additional criteria and broader evaluation.

Then on this proposed initiative there was point feedback on many of the initiatives. We've actually taken, at least for the two initiatives that we launched post that public comment, we've actually taken the point comment and used them to refine each of the initiatives. We got a broad range of comments that ranged from pretty much the whole gamut of the HIT community.

Next slide. So what did we do? We took that comment and, as I said, we updated the initiative descriptions for two of the initiatives that we're launching. There's a third one that's a little mysterious here and we'll explain that as we go. So we've also taken back the prioritization framework to address

the privatization framework in the context of …of the comments, and we'll have a new iteration of that prioritization framework that addresses the feedback.

On Friday, we issued a call to participation for three initiatives, a transition of care initiative, a lab interface improvement initiative and a consolidation project initiative. I'm going to actually go a little out of order in the way that I discuss those, but we put together initiative charters for each of those initiatives and I will describe those. So if I can go to the next slide.

The first one is the lab interface improvement and here we note that there is, there's actually a pretty decent selection of well-defined, U.S. specific specifications for lab data interoperability. There's one that came out of the ONC funded ELINCS work, or ONC initiated ELINCS work that went through the CHCF, the California Health Care Foundation, and was validated ….7.2.5.1 specification named the R-1 specification. And then another actually ONC sponsored initiative through HITSP and a finalized specification that is the U.S. Realm 2.5.1 implementation specification. So we've actually had a wealth of implementation specifications, which leads to the joke of the great thing about standards is there are so many.

But if we look at the actual practice of …interoperability across the country, what we see is loss of variation and loss of use of integration engines and the like to harmonize between the labs' view of the world and the EHR's view of the world. And I think we're hearing lots of feedback from, for example, regional extension centers as well as implementers that there's a ton of complexity involved in information exchange related to lab reporting. So this initiative is focused specifically on ambulatory lab reporting and it's focused on providing a single, well harmonized comment specification for lab reporting that can be agreed on by the key stakeholders in the lab community. And I'm sure people who have been involved in the HITSP process or been involved in CHCF process, say, "That's great, best of luck." But I also think people who have been involved in those processes understand their critical importance of this in achieving the requirements of meaningful use in broader healthcare transformation.

What we're doing here, these costs and time reductions are subject to initial stage review and analysis. But the target outcome is a meaningful reduction in the cost and time to implement a new lab interface as well as broader meaningful use achievement related to incorporation of lab results, as well as supporting meaningful use objectives for decision support, quality reporting, transitions in care and electronic copies of clinical summaries to patients. That is, we really need to be explicit about the expectation that the lab data that comes in can feed in all of the downstream processes that are necessary and that requires us to look at things like vocabularies and the like.

Next slide. I'm actually, if you go to one more and then we'll go back up. So the S&I framework actually coincided with some work that HL-7, IHE and the Health Story Project decided to undertake to look at CDA consolidation, and in particular look at the implementation guide for the C-32 specification for CCD. As many people know, the standard certification final rule pointed to C-32 as the normative specification for the Continuity of Care Document, the CCD. And the C-32 was some assigned work that was done through the HITSP process that itself pointed at a number of other documents, including C-83, C-154, and then those documents in turn pointed to work that had been done through IHE and work that had been done through HL-7 and the Health Story Project.

The net effect for implementers is that there's a tremendous amount of information and guidance and advice, but that it is in multiple places and requires some art to pull it all together. Now NIST has done some incredibly fine work in the context of validation tool kits for meaningful use to pull that together and provide good validation context for meaningful use for the C-32. But we can and will do a lot better and HL-7, IHE and Health Story actually jumped in to volunteer to consolidate all of the templates that are informing CDA, in particularly in forming the C-32 and C-83, to make sure that they're harmonized, to make sure that any of the issues that may appear, inconsistency between the templates are ironed out and provide a single consolidated implementation guide that pulls together all that material.

Because of the timing, we decided to look at that in the context of the broader S&I framework, but recognize that that is a very focused initiative that's really focused on that subset. If you go up one slide,

the work that's being done in that CDA consolidation will inform the transitions in care. So if you can go up one slide, please. Thank you. Will inform the Transitions in Care Project. And here the goal is to make sure that implementers who implement either the CCR or the CCD have a well-defined, normative set of specifications that identify how to identify the meaningful use required data elements in transitions in care. Regardless of the actual document type or document template that's used in that transition of care. So, for example, the broader data needs that inform a discharge, the inform transitions to long-term care, that involve transitions in certain specialty care may actually require the creation and use of specialized templates or specialized packages of information. But there is a core set of data that needs to be transmitted in every transition of care to qualify for the meaningful use criteria. And to the extent that those are and should be done electronically, it is a vital importance to make sure that there is strong, normative specification for exactly how do you package that core data in transitions of care. And to set expectations, for example, of the point element people have struggled with as to how to handle a complete med list versus how to handle a set of medication changes. For example, if I get discharged from the hospital and the hospital has performed a full med reconciliation, I may have a complete med list. If I have been transitioned in care from specialty care, the specialist may actually just be transmitting back the changes to my medication. We need to know and understand exactly how to transition a medication list, a problem list, and all the other required elements for meaningful use, regardless of whether I used the C-32 document or use a different CDA template or use the CCR.

So that's the Transitions in Care Project. Again, the outcome here are to enable electronic transition of data and to ensure that organization that validate their use of CCR or CCD in the context of meaningful use certified EHR have strong assurance that parties that have also implemented the same function can incorporate that data electronically and use it to inform clinical care and improve clinical quality.

So that's a very high level view of the first three initiatives that have been launched, with the two main initiatives being the lab interface improvement and transition in care initiative, and the CDA consolidation project being a really important set of focus effort on the C-32 and CDA broadly.

If you go down two slides. So where are we going? We're going to be continuing to measure the two or three launched initiatives, measuring them by process outcomes, that is how much engagement do we have, how much participation do we have, how quickly are we going through the work and then, more importantly, outcomes and value measures. And making sure that all the work that we're doing is tying back to an improved health care system.

We will be refining, as I mentioned, the prioritization framework to be able to accommodate the feedback that we got. And then we likely will be launching additional initiatives. So making sure that we got strong alignment to both stage I and to the Policy Committee's work on stage II meaningful use, and to make sure that we're aligning with the Policy Committee and Standards Committee recommendations in other areas. And I would note, in the remainder of the day to day of the Standards Committee you're hearing on directories as well as on certificates and we believe that there may be work to be done there or aid that the S&I framework can provide in those two areas as well as in the recent discussion on PCAST to the extent that the Standards Committee has recommendations that stem out of the PCAST work.

So, with that I'm going to open it up for questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President
…Cris to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
First, let me thank Arien and Doug for their terrific work in creating the framework. One of many new institutions – it sounds like a very momentous word, institution – one of many new processes that we've created at ONC and that we hope will continuously improve. Maybe I could ask each of these use cases that you've identified for the development of frameworks is independently important and the emphasis that you've placed on outcomes, value added outcomes is critical because actually, of course, the standards are not valued in themselves, they're valued for what they can enable people taking care of patients to do in the real world. As you see these three projects and the others that you're working on

coming together over 2011, what do you see them in total enabling clinicians and other users of health information to be able to do? Can you summarize a kind of revised state of the world that will be made possible by this very, very impressive work that you're doing?

Arien Malec – RelayHealth – VP, Product Management
That is an excellent question and I would, as you know, always go from outcomes backwards. So the state of the world that the interoperability and that the S&I framework is trying to drive to is a state of the world that's defined. I love the way that Don Berwick defined it as, "Improved care for individuals, improved health for population and cost reduction through improved quality." And in particular, with these first two initiatives and then with the broader set of initiatives, the expectation is that providers can meet their meaningful use obligation and meet the broader set of quality improvement obligations that are tied to meaningful use.

So, for example, with the incorporation of lab results electronically, there's a process measure that providers can meet, but also a broader set of quality measured including reductions when people get testing, including quality improvements through access to lab data, including public health improvements through access to quality measures that are driven or associated with lab measures, and then improved transitions in care to the extent that there are referrals or other transitions in care that the lab data that's been received electronically can improve the quality of each transition in care and improve the quality of the patient care across multiple settings of care.

Likewise, clearly, for the Transitions in Care Project the focus is on improving the care of the patient, not just at one setting of care, but across all the settings of care where the patient is seen. And ot make sure that the care of the patient is improved holistically as well as to make sure that that data is available for improved decision support and improved population health management through its inclusion in quality reporting.

Doug, I'd invite you also to comment. From the teacher.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thanks, Arien. Tremendous summary of all the work that's going on here. I think you're absolutely right, the goal here is to help enable a seamless information exchange. In many of the initiatives that are being launched, that were launched last week and that we are hoping to look at and potentially develop over the course of the next couple of weeks are providing that foundation and some of the critical elements that need to be done.

I think it's important also to note that the consolidation project is really, in many ways, unique. We have two standards organizations that really are coming together. And I think one of the clear value that that project is intended to bring is around making the work simpler and by making the work simpler, making it easier for the capabilities to be available to the physicians to use. And so there is a focus on reducing that complexity and providing clarification and sort of giving people the advice about what they can do to enable the functions that providers need.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much for that terrific exposition of the work of S&I. I can't help but be struck by two things. First, John Halamka, in your opening comments remind us the attendance to the internal workings with respect to content, vocabulary and transport. Arien and Dr. Blumenthal both described the interdependence between use cases, which must synergize to create the ecosystem that Kevin Hutchinson had alluded to.

I look forward to conversation on this. I want to make sure we don't neglect our colleagues online, so let's start there if anyone wants to weigh in. Then we'll go around the room here in Washington.

John Halamka – Harvard Medical School – Chief Information Officer
If I could just start with a comment, and that is that for each of those three individual projects, I absolutely see the need, from my own work trying to get Beth Israel Deaconess certified for meaningful use. With

regard to the CDA consolidation, I had an issue yesterday, which is the HITSP C-83, which was quite well done for its time requires SNOMED as the vocabulary for the problem list. But of course we have the final standards rule, which says that SNOMED and ICD-9 are both acceptable. And so if an implementer goes to C-32 and that then points to C-83 and C-83 says SNOMED is required but then the regulation is different than the standard, it creates an implementation challenge, which NIST yesterday clarified beautifully with what needed to be changed. But to the point that Arien made, if we could eliminate indirection and have a single, crisp implementation guide so a vendor can open a single document and have everything that is necessary for implementing this CDA, that would certainly make life much easier.

On HL-7 and specifically lab I haven't had quite a good experience with 231 and 251 transactions. My challenge has actually been on the compendia; the notion of having a single, orderable vocabulary for the 98% of the most commonly ordered lab tests. So today I have to do integration among multiple built and bought systems from multiple vendors, and on average I am spending $5,000 to $10,000 in project work because the compendia do not coincide between the various systems, inpatient and outpatient. So that's really an area of focus for me. Less so much the content standard, more the vocabulary standard.

And regarding transitions of care, it is interesting that our discharge summary has such things as "diet recommendations," "activity restrictions," "followup information." Very important that its standard for a transition of care document, but the purpose of the initial CCD or CCR was to include a point in time summary. So it doesn't necessarily fit with what are some of the what I'd call templates we are wanting to transmit to the next provider of care. So working on a template-based mechanism to easily assemble those data elements that are necessary for transitions makes great sense. I certainly applaud those three initial priorities.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. Again, a resonance with many of your comments for those in the throws of implementation. Any other colleagues on the committee online that would like to weigh in? Okay, then let's go to Kevin Hutchinson here in the room.

Kevin Hutchinson – Prematics, Inc. – CEO
So first area, Doug, I'm thrilled to see the priorities that you set forth with the lab and the transitions of care and the CDA, because I think those of all the priorities we could look at from an information exchange basis would have probably the most visible benefit as we look at care management and care coordination. I think those are great.

One of the comments, kind of going off of David's comments about the use cases, I think there's going to be some interesting things that could come from, as we pursue this path and these three areas, we talk about how we're looking at this from a quality of care basis, but I think about a more coordinated care environment and the impact it has on a patient's psyche. A lot of patients who may not be compliant with coordination of care or care management requests because of the hassle factor with going from one place to another, and filling out additional information, and you see people may throw their hands up and say, "I'm okay." And the reason they're okay is because they just don't want the hassle of that next coordination of care because of the uncoordinated fashion that we have today in healthcare.

So what would be interesting is as we look at the use cases and we're going to get more clarity and definition as to what we want to get out of those use cases, I think quality of care is a great measurement, obviously, but also the impact that it may have on patients' ability to be more compliant with those care guidelines or those care orders because it is a more coordinated environment, more efficient use. So it's something to consider as we look at the use cases.

Going to John's comment, I had already written down a note around the CDA. I notice have in here combining into a single library of templates. It seems to me if we could get a place, and this is what I think John was referring to, where there's a single document that could be used many times versus a library of templates that could be used a few times will probably have a larger success of getting this implemented at an industry level.

Arien Malec – RelayHealth – VP, Product Management
First of all, I am chaffened not to have mentioned the role of the individual in the care delivery process. I've done work in the past on that very topic and I understand the fence with which interoperability is key to providing patient engagement. So, for example, I've done work to ensure that patients on every lab order get access to, as appropriate, the lab test results. And I know firsthand, from my own experience as well as hearing the experience of patients, how much more engaged patients are in their own care when they get simple things like access to their own lab results and the ability to incorporate lab results electronically is a foundational element to being able to provide that level of engagement. So I completely agree there.

In terms of the statement there should be one or only a few templates, I think the way we're approaching it in the context of this project is to say that there should be a core set or a core common set of sections that are appropriate in every transition in care as defined by the requirements for meaningful use. In my own work, I've been involved in the nuances of different transitions in care that sometimes do require specialized data and I don't know that we want to limit or inhibit improvement, innovation in being able to carry, for example, plans of care that are specialized to particular environments. But, I would completely agree with you and concur that regardless of what template or what package of data is being sent on a transition of care, there is a common core set that everybody should be able to write and everybody should be able to read, and everybody should know how to define and to incorporate electronically. So just with that nuance of interpretation, I completely agree.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's move on to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Hi, Arien. I just wanted to make a particular comment on the lab effort that you have going on. I am one of the folks who was involved in both of those specification development efforts that you mentioned, and one of the reasons why there are two different ones is they're intended for different purposes. So I think it may in fact be a mistake to try to harmonize those if they're really intended for different things. It's probably more a matter of picking what the real use case is. And I'll just point out a couple of particular differences.

The ELINCS use case is intended for easy implementation between a single EHR implementation and a single laboratory and that's what it's for and I think it does that very well. By design, that …does not include the information that's required for public health reporting, information about the patient visit or the provider details, but commercial labs don't want to carry that extra data. And it also uses local codes of the EMR that, again, make it non-unique. So whereas the other specification, the interoperability spec, that one is intended by design to include reuse of the information for public health, population care and other reporting purposes, and it's also intended to be used across multiple providers. And so by definition it includes unique identification of orders. So, there are a bunch of things that are different about those two specs, but they're intended for different purposes. And so I think in an effort to try to harmonize across those is really, in my mind, it's more a matter of deciding which use case you're really trying to solve, because they're different for a reason and they're both good for their intended purpose.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks for those comments. I know just…the preceding discussion that the conundrum that the broader environment face is okay, but at some point there are intersections and how can we transcend the specific …of each use case and the derivative architecture to really move forward to a world that is asking for such a greater level of interoperability. I'm sure …on that point, I'm sure we'll have discussion on that. Let's go to Judy Murphy next. And then Wes, we'll put you in line there.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Arien and Doug, wow, this is just fabulous work. One of the concerns that I have about the work is disseminating it appropriately and making sure that all the folks that really need to understand it and understand, as John Halamka would put it, the glide path towards this is out in the general implementation. So earlier this morning I mentioned that there was confusion related to health exchange

and data exchange voiced by the implementation testifiers yesterday, and it wasn't just about what health exchange I should be linking with or using, but it was also around this what exactly should I be doing today and how does that move me towards where I know I need to be going tomorrow. So the word "roadmap" was used quite a number of times. It was used in relationship to the meaningful use criteria itself. But it was also used related to health exchange and how the pieces that I'm expected to do in stage I criteria today is going to be getting me where I'm going tomorrow.

So as you were presenting, I couldn't help but think how many people know about your work, do they understand the little pieces that they're doing today in stage I and how that's going to drive them towards true interoperability as exemplified in the S&I framework? And I think part of that answer to that is getting broad dissemination of these three use cases that you were talking about today and showing folks how those are examples today of what they could be doing in stage I and how that's going to be feeding into what's going to be expected in the bigger picture.

So I guess to distill my question down, the dissemination strategies for this, do you guys have thoughts on that?

Arien Malec – RelayHealth – VP, Product Management
We did attempt to get the initial invitation out to as broad an audience as we knew how through the various mailing lists that we have access to through, for example, the state HIE programs, the REC programs, the National eHealth Collaborative, the Direct Project, the various STO's. So we tried to the extent possible to get a broad publication of the S&I initiative out to as broad an audience as possible. I'm hoping this meeting with all help to the extent that both folks who are listening now or will be listening to the rebroadcast, and to the extent that members of the media are in attendance and can also help get the word out.

Then all the work that's been presented here is available in the public in wiki.siframework.org, and we commit through the S&I Framework to make sure that all the work we do is open and transparent, so that people who need to have access to have information at least have a single place to go to be able to pull that information down.

And to the extent that all of you can help get the word out, I think we'd all appreciate that.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Just to follow on to that, I'm personally feeling more of a push than a pull. And the push to me might be to use the RECs and/or the state HIE infrastructure to do that, because I'm not feeling, in my own mind, anyway, a lot of harmonization between those efforts.

Arien Malec – RelayHealth – VP, Product Management
It's actually interesting, I've been involved in a number of state specific work where we actually have gotten the, in many states, actually, there's one person who wears two or three hats and in those cases dates and RECs are really well aligned. It's really the larger states where you've got a lot of complexity. And I've seen actually a lot of really positive work where the rec and the state HIE work are incredibly aligned in terms of the REC saying I've got a bunch of providers who need to achieve meaningful use, they all want access to lab data, so let's focus on how do I get electronic lab reporting out for all the labs. The state is in a position to enable electronic connectivity for critical access hospitals, for state hospitals, for public health labs and the like, and so we're starting to see a lot of really good alignment there. I'll point out a project that's being done through North Carolina between the North Carolina HIE and the North Carolina REC that is in fact aligned around electronic reporting labs. …care.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Mark Overhage.

Marc Overhage – Regenstrief – Director
Thank you. I'm struggling to make my comments and questions concise, but I probably will fail. I think the core question or concern that I have is it feels like this is the nth iteration that we as a country are

going through trying to create a framework implementation guide and so on to meet the needs of the providers that are out there. And the implication always seem to be, and John Halamka highlighted this specific example, of while SNOMED is listed as a standard in an implementation guide, but now maybe we need ICD-9, so we've got to go back to the drawing board. And reflecting on while I wasn't able to participate in the hearings over the last two days, what I've heard from folks who did was the sentiment is we don't know where in the heck to go.

I'm concerned, fundamentally we're saying the problem is we don't have enough frameworks and implementation guides, or it's not the right framework and implementation guide, or something. But I don't hear that from our constituencies, from the vendors, nor from the hospitals nor from the providers that we're lacking in those things. And I think this comes in part from two schools of thought, perhaps. One is I'll call the magical thinking school, and it sounds more pejorative than I intend it to be, that if we just got the right standards, everybody could plug everything together and it would work. And I don't think that's a reality because there are operating systems, whether it's in the VA, whether it's in long-term care facilities, whether it's in hospitals and doctor's offices, John Halamka highlighted the example of lab compendia today, that are going to have to be worked, managed and massaged no matter what the vehicle is. So I think for at least five, ten, maybe even fifteen years we're going to continue to have heavy lifting to do to get things to work together.

The other school of thought seems to be that we just got work to do, so quit confusing us, quit confusing the people that are going, quit asking a new set of questions because then I stop doing the heavy lifting while we figure out whether this is the next thing to sliced bread. So long-winded introduction, sorry, I tried to be brief. So the fundamental question I have is, what problem are we solving with this set of activities? I knew what the problem is, I think, at a large scale, and that is that we don't have broad spread adoption of whatever it takes to get interoperability. Is this going to actually advance, is it going to provide fundamental change, because we've done it five or six times before. What's different this time so it's going to get us somewhere?

Arien Malec – RelayHealth – VP, Product Management
I'll do one comment and then turn it over to Doug. I'll turn it over to Doug for all the hard problems.

I think it's an excellent framing. I do think there are things that are different now. I think meaningful use is different. Speaking as a former HIT vendor, I know that in many HIT contracts these days service, and in particular, for example, putting together the lab interface is a core part of the contract that is sold. And revenue recognition, for example, is held until the service is performed. So there's a much more of an economic incentive that harmonizes, if you will, interest.

I also think that there's a broad enough adoption at this point of electronic health records in the community that is not standard looking for, it's not sockets looking for plugs anymore. We've got sockets and plugs and we just need to, you know, okay, enough's enough, we need to make sure that the sockets fit into the plug. That is, there's enough of a critical mass right now where standards have a place to hook in and go.

I guess the third thing that I would say is that speaking as an implementer trying to solve problems, my guidance to my teams would always be we're going to solve problems. If there's a standard that helps us solve the problem, let's use that. If there's not, we'll figure out how to do it ourselves. And in the context of your second class, the non-magical thinking category, too many standards is just as much problem as not enough. To the extent that I've got two or three different ways of knowing how to do this and I'm not, somebody who's enmeshed or immersed in the standards development process, I'm going to throw up my hands and solve the problem. So, I do think that there's a set of changed circumstances, both in terms of meaningful use and in terms of the prevalence of HIT that does make the situation different. And I do think there's a whole set of people who are looking for, you know, you're not going to solve every problem, you're not going to be able to address interoperability of every single anolyte that's attached to every single machine or instrument, but we have a critical need for …to receive A-1C's. And as you call it your reporting of A-1C's. So around specific domains there should be one reasonably good answer that we can just pick up and run with.

And I do think that pursuant to the discussion on the Implementation Workgroup, I've heard that as a common theme of you're not going to solve every problem, but at least for some subset of problems it makes sense to have one obvious solution. And if we can create that, I do think we'll see decent adoption of it.

Doug, I'll turn it over to you.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thanks, Arien. You've given a good summary.

I think one of the things that's important is the drive towards the value to make it focused. This isn't intended to solve all the world's interoperability problems, but I think it's intended to help organize and focus our approach to solving a problem that this committee and others come to us and say, "These are the things that are barriers and that we need to move forward in solving them." So, I know that there have been a lot of initiatives before. I think the focus here isn't that we have yet another framework. I think it is, however, with complex problems trying to do them in ways that can be inclusive and can help coordinate all the parts requires us to get organized. And this is really an attempt to organize our work, help support the needs that this committee and others will bring to us.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I want to be respectful of time. Recognizing that this discussion is very much inseparable for the work of the committee going forward, and this will be a conversation that continues, so I think we're unlikely to answer perhaps the unanswerable today, but let's take four more concise comments. Marc Overhage following Steve Ondra. Dr. Ondra wants to weigh in. Dixie Baker. And Wes, let's go to you after we go to Marc.

Marc Overhage – Regenstrief – Director
This one's a comment. I agree, Doug, with your assessment about organizing and driving. The disconnect for me is how the activity helps that. So I'll leave it at that and let the other discussions dive down a little deeper.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Wes Rishel next.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I want to first of all reinforce Marc's comments by pointing out that sending lab data is the most widely held problem other than e-prescribing in terms of standards. I think e-prescribing had it easy because it was n to m, but n was a very small number.

In fact, what we're really saying in regards to the lab is not that we can't do it now, but that the cost of doing it for NSA's, for instance, is too high and that has a little bit to do with format and a lot to do with compendia.

I think the process we're going through is not going around in circles, but spiraling upwards to the extent that this current initiative is responsive to one of the biggest lessons we learned in HITSP, which is the fact that you needed 14 fingers on each hand in order to put your place in all the places in the books where you needed to write a spec, I mean, put the right code from the hierarchy of specs that were used.

Going back to the discussion between Jamie and Jonathon that started this go around, Jamie described there being two specs for two different situations and Jonathon said, "Well, that's a problem that we have to respect." He didn't say it that way, but I took that implication. I think we have to recognize that the difference between the two specs has to do with the cost of operating a lab; how much data is collected for the benefit of the recipient of the message as opposed to how much data is collected for the benefit of doing the operation in the lab. It's been my experience that I can solve almost any problem in the world if

I get somebody else to do the activities that are required to make the solution. And that is a consistent problem in interoperability that we say, "Well, you can solve my problem if you collect the data."

So absent a recognition that there will be different cases based on the business conditions surrounding the use of a standard, I'm not sure we will get the useful standards. I think that an option to consider through the S&I framework is to not only have to once and for all a single document where the specification is written, but to also have effectively a triage in documents for standards and variance. I don't think this has to be particularly elaborate, but if we really find that the business implications of implementing a given standard is to drive the cost of daily operations up for some party, like labs, then we need to consider our options there.

So, we learned how to send lab data 20 years ago. We learned how to create a spec that for the well-informed reader has all of the information we need. Now we're trying to learn how to make a spec that has all that information and is going to be read by a mortal. So we're spiraling up in some sense, but I do think we also have to consider the economic consequences of the decisions we make on the participant. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Wes. Let's move to Dr. Steve Ondra.

Stephen Ondra – NeHC – Senior Policy Advisor
Thank you. Very interesting discussion. And as we circle in on different standards and standard documents, I wanted to touch back to the consideration of the full ecosystem again.

Arien touched very briefly on some of the issues of consumer aggregation. So as I look at this, there's two very broad categories of health information exchange – provider-based exchange and consumer aggregated health information and the exchange and reuse of that. I think it's very important that we consider the role of these standards and standardized documents in the consumer aggregated part of that exchange, and how that is then reusable in a meaningful way by the providers of those consumers go to.

We tend to focus on the provider-based exchange. I know I do as a physician. And many of us in this room come from either the health industry or the vendor industry world, so I think it's important that we also remember that piece of the consumer aggregated part. I know that I'm certainly not smart enough to know how the future is going to look. If I did, I would have done better on the …with the bowl games. So I think it's important that we consider that whole spectrum of things …

And last, just one comment. There was a comment on sharing of lab data with consumers as appropriate. Speaking as a provider, I'm trying to think of a single example when it's not appropriate to share consumers data with the consumer. And so I think we kind of moved off the when appropriate and if it's your data, it's your data.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's move to Dixie Baker for the final word. Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay. I'm sure that I have no guess that developers will really appreciate having available to them a single document and a set of templates that they can use to implement a lab interface or a particular CDA, but I'm wondering how the fact that standards are always evolving will be handled. All of us know, standards aren't static, especially vocabulary standards, and they change at different times, over time. And I'm wondering how you envision addressing that issue? Have you developed a process, a mechanism or how will that be addressed?

Arien Malec – RelayHealth – VP, Product Management
This one I'm definitely going to turn over to Doug.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thanks, Arien. Right now it's approaching 3:30 in the morning in Sydney, and so I can tell you a bit about the future. The sun hasn't quite come up yet, but the day looks nice.

I think you're absolutely right, Dixie, is that if we want to talk about sort of magical thinking, the idea that can do this one thing and be done is sort of unlikely. And so there is a need to have a continued involving set of specific…and standards and to be able to manage those effectively. I think one of the hopes is that by creating some consistency in how we represent that information so that we can share with other people who are developing complementary standards or have a …way of representing it ourselves to make this easier for us to put in the tooling and the infrastructure to help maintain both consistency and …as we move forward.

When it comes to things like vocabularies and terminologies, I think that becomes even more critical in that I think we need to identify those organizations or groups that can be considered stewards of those value sets or those vocabularies and terminologies, and then provide a mechanism or sort of incorporating and consolidating those into these documents or these implementation specifications that we …

So, it's sort of a long answer, but I'm not sure that we have precisely the … We recognize that it's an important issue that needs to be addressed, and the hope is that by getting a process and other facts that are consistent and identifying stewards and ways of integrating this that we can address that issue going forward. I anticipate that this will be something that we will refine as we go forward as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll go for our very last, last word from Linda Fischetti.

Linda Fischetti – VHA – Chief Health Informatics Officer
Thank you. Just to the last question from Dixie, as a member of the Policy subcommittee from Nationwide Health Information Network governance, that's an issue that's come up recently. And while I don't believe the Standards Committee has had as many cycles with the Nationwide Health Information Network governance committee as we have had with the Policy Committee, that's probably an important conversation that we want to have from the Standards Committee platform.

Jonathan Perlin – Hospital Corporation of America – CMO & President
This has been an extraordinarily rich discussion. I think the very questions that everyone put forward, Marc and Wes in terms of challenging the complexity, while not magical thinking, I think the comments, the contexts that are different are really drivings for action in each of these areas that will dictate a good bit of work and discussion in this forum and that with our colleagues in parallel committees. I appreciate the thread that was raised of the patient not being excluded, the importance of consumerism and access to information. Nothing left out of this exchange. Nor the importance, as Wes reminded us, that the ecosystem is not devoid of economic value implications when standards development or the implication of standards development leads to certain specific activity. And in fact, Kevin Hutchinson reminded us earlier that with the appropriate framing this cannot only not be, not to be pejorative here, not be harmful, but can actually incite activity and investment, and that's terrific. And then the last thread that Dixie reminded us is that the ecosystem that we're describing is not static in terms of harmonizing what's there, but this universe, by definition, is expanding in terms of what will need to be updated or modified with additional learning, technology and innovation, etc. Back to Marc's point, that doesn't make it easy and there probably is no good answer.

In terms of my own personal reflection, I think the context is so much different that there's an urgency. It doesn't necessarily make it easier, but at least it creates a broader motivation that's shared amongst a number of quarters. That gives me optimism about the future role.

I want to particularly thank—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Sorry, it's Carol. I've been trying to get in, but …remote challenge is a significant one. I just wanted to make one very quick comment, if I may.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Go ahead. Very quick.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Very quickly, with all the references to magical thinking, I felt that if I could just say that the key point that we made in that paper, in the House Affairs paper as it relates to standards, actually the point that Dr. Blumenthal made in the earlier question around the business case for information sharing, I just wanted to say that more and better standard specification almost never creates incentive to share information, but the imperative to share information, which in turn creates demand for more tools and standards, is more the likely scenario. And I think the more that the efforts of ONC can be aligned with other opportunities to create that imperative, whether it's ACO's or payment reform pilots or the Beacon Grants or what have you, the more likely it is that this and other working standardization will continue to progress. But specification is clearly only one piece of it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Very well said. I want to thank Arien Malec for laying out the exposition of the S&I, the interrelationship with the other committees and the Office of National Coordinator so well. Thank you for your work and leadership. And I want to thank Doug Fridsma for…as it is indeed 3:00 in the morning and he started to call probably about 1:00 in the morning in his local clime, and thank him for that. I also want to thank and note that both Doug and Arien will be speaking really back on the first principles that David Blumenthal alluded to about advancing quality and safety on the National Patient Safety Foundation conference call on the 19th. I publicly acknowledge them because we shouldn't lose sight of really the first principles about patient care.

We're a little bit behind, but we've got some schedule flexibility. I want to turn over to John Halamka for introductions of the Directory Standards discussion and some real world experience as reported from the Information Exchange Workgroup. So John.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much. So just as a brief introduction, suppose that I want to send a message to John Perlin at HCAhealthcare.com? Is there today a national directory that enabled me to discover where John Perlin, the person, is specifically located and what address I can reach him at? The answer is, well not really. I have a contact list in my email client, but once I send John Perlin an email, there is a national system that routes from bidmc.org to hcahealthcare.com and that has been sufficient to enable commerce between me and John. So that is to say, for email in this country we have an organization or entity to entity directory system, not an individual to individual directory system. And so as Walter and Micky describe the request to the HIT Standards Committee, recognize that there are two real problems to solve. As we wish to push healthcare data of all kinds in a directed fashion from lab to EHR, to doctor to patient, from doctor to public health, there are use cases in which an entity to entity directory structure will work very well. And there may be use cases in the future where an individual directory system that may be of a more federated variety will also be desirable. But one does not need to start with an individual to individual directory structure to be again commerce. We can start with something simpler.

So Walter, look forward to your comments.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thank you very much, John, for the introduction. I'm going to turn it to Micky who is going to make some introductory remarks and then I'll take it after his remarks. Micky.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Okay, great. Good morning, everyone. Sorry I can't be there in person. I'm snowbound one town over from John Halamka and we're doing this from the winter wonderland up here in Boston. So I just wanted

to give some very high level introductions to the Information Exchange Workgroup that I'm the chair of and then turn it over to Walter.

John Halamka just gave a great introduction to the problem that we're going to discuss with you today. Looking at slide two, what we want to accomplish today is to introduce you to the general charge of the workgroup in the task force, focus on provider directory; give a little bit of background information on the provider directory delineations that we've come up with, which is to say that any level provider directory that we're going to discuss in greater detail today and which the Health IT Policy Committee has made a set of recommendations about; then the so-called individual level provider directories, give some background on and are a part of our deliberations right now and in which we're anticipating copying a set of recommendations before the HIT Policy Committee sometime in February or March.

I wanted to specifically present the policy recommendations on the ELPD's as endorsed by the Policy Committee, because there are some very specific requests there for the Standards Committee. And then finally, give you a little bit of preview on the thinking that we're going to be doing, that we're engaged in right now on the individual level directories.

So if we could turn to slide three, the general charge for the Information Exchange Workgroup is really sort of two forms. One is to identify breakthrough areas where policy barriers might prevent providers and/or states from becoming effective enablers of broader and deeper health exchange. So those are sort of where we ourselves as a workgroup identify things that seem to be working in conjunction with the ONC staff. There seem to be obvious areas where there might be breakthrough opportunities. So last year we focused on e-prescribing, and labs in particular as two areas, and had a set of recommendations related to those.

The second sort of source of charge for us is acting as a conduit for state level policy issues that are starting to emerge as the state level HIE programs start to get underway. With 56 activities out there now, plus the Beacon, plus the REC's, there's a whole bunch of implementation activity that's really just starting to get underway. And I think as all of us who have been in this know, a lot of the policy issues that are important aren't recognizable until you start doing the implementation work and they start bubbling up.

I would categorize the provider directory conversation as being a little bit in that latter category in that the state level program in particular have been given strong encouragement from ONC to use some of their funds for provider directory approaches in their state level programs. And so the requests starting coming up really from the bottom up for some type of direction for provider directories, and that's what we're responding to here.

On the next slide, slide four, this is the entire Information Exchange Workgroup. My co-chair is David Lansky. You can see here a pretty broad representation across sort of all parts of the healthcare delivery and health IT value chain and want to commend the workgroup for all of the work that they've done, all the time that they've put in into this issue.

Move to slide five, the high level policy objectives that we're trying to solve with the provider directory conversation is much like the other areas that we focus on, which is how do we facilitate a rapid increase in health information exchange through the health system, through some specific recommendations provided… We know the lack of a consistent approach to cross organizational provider directories is a barrier to progress, both in directed exchange as well as in health information exchange more broadly. We also are concerned that there could be a missed opportunity to align multiple activities and combine multiple streams of funding that could yield a lower cost, higher quality service for all. So as I already described, you have state level HIE grants, Beacon Grants, REC's, you have some sort of level of program where they're thinking about this, but we also have non-ONC funding streams as well, like Medicaid and public health who also have a specific amount of money that they're allocating towards things that are like provider directories or could be greatly enhanced by more robust provider directories. So there's an opportunity here to be able to try to get this more aligned in a way that would make it more effective and more efficient.

So the key questions that we're addressing as a workgroup were these four questions here. How can provider directories accelerate information exchange? What could federal and state governments do about it? What policy actions can be taken to promote the creation of provider directories and accelerate exchange? And then finally, the question of costs …border and nationwide in health information exchange and how can that be accelerated by consistent application and use of provider directories.

So, as the chair of the workgroup, I quickly recognized that this was a very difficult problem and so I immediately scrambled to find two people who could take it on and take the burden off of David and I. I was fortunate enough to have Walter Suarez and Jonah Frohlich both be willing and able to be the co-chairs of a task force that is now spearheading this effort. So on slide six you have the list of those who have been willing to spend a bunch of time on it on the task force and now let me turn it over to Walter to lead us through the rest of the presentation.

I should also mention that Jonah, who is the co-chair, is on the phone as well for backup, I believe. And before I turn it over to Walter, I just want to thank both Walter and Jonah for their tremendous leadership and the incredible diligence that they've shown in getting us to a set of recommendations that I think we're all very happy with and that we hope will be sort of pushed forward by the Standards Committee.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thank you, Micky. Thank you very much for that intro.

I have to say that when I was looking at this I thought, well, what could be so exciting about provider directories? I have to say, after going through the last three or four months of discussions, I have rarely seen such a thoughtful and dedicated engagement of this group of people, their expertise. I think the list that you see on the slide fails to show a couple of other people that have actively participated. I wanted to just mention them very briefly. Carl Dvorak from Epic as well as Arien who help us quite a bit in understanding provider directory approaches and issues currently underway. And we coordinated also significantly with the work that the Security & Privacy tiger team have been doing, particularly in the area of …certificates and the recommendations that are coming back to this committee from that side as well.

Now, very briefly, provider directory, what is provider directory or what do we see is the definition of it? Most people have used the reference back to, for those that still remember, the concept of Yellow Pages and White Pages. Ultimately that is indeed what we're trying to address here is to establish an electronic searchable resource that lists information about those participants that are going to be exchanging information, both in terms of organizations as well as individuals. So this definition is the working definition we're using.

We quickly, when we started working on it, distinguished the two major types of provider directory that Micky mentioned in his introduction – the entity level provider directory, which is a directory listing organizations and then the individual level provider directory. In the next slide, this is sort of the framework and then the roadmap that we work on. We started looking at recommendations. First, this applies both to the entity level as well as the individual level, but we started certainly focusing on the entity level provider directory. So you can see, we tried to identify the users and users of this directory, the functions that they will fulfill, the content of the provider directories themselves, and then what are some of the operating requirements and business models that will be needed to be put in place in order to advance the adoption and use of this provider directory and that led us to some policy recommendations.

So we took this framework and applied first to the entity level provider directories and developed the first set of recommendations. You can see at the bottom of this slide. They were presented to and endorsed by the Health IT Policy Committee last month. And we're now working on the individual level provider directory recommendations.

So, let me go into the details of the entity level provider directory recommendations. So you will see there are recommendations in each of the major areas that we discussed. So first of all, on the users and uses, the recommendation was primarily to identify the type of entities, because it is an entity level provider

directory, that would be made part of the ELTD's. And so we listed them here as primarily the entity that would be engaged in an electronic exchange of health information, the healthcare provider organization, such as hospitals, clinics, nursing homes, long-term care, pharmacy, labs. Other healthcare organizations including health plans, public health, health information organizations, entities that are maintaining and supporting the operation of health information exchanges as well as health information service providers. And then other organizations involved in the exchange of health information, such as business associates…houses and those.

So this would be primarily the entity that would be listed in this entity level provider directories. With respect to the functions, their recommendation was to support the following key functionality. First of all, support the ability to conduct directed exchanges, whether it's send/receive or query/retrieve exchanges. Secondly, to provide basic discoverability of the entity, the ability to discover which is an entity that this message is going to go to or that I need to go to to retrieve information. And then also provide basic discoverability of two other major aspects, the information exchange capabilities and features of the entities. So, for example, an entity that will say I'm able to speak CCD or HL-7 to… So those are features that would be expected to be included in the information of the entity level provider directory to support that functionality as well as discoverability of the security credentials. And here we wanted to make a clear distinction of we're not saying that the entity level provider directory will provide the actual certificate or credentials, but it will just allow then the entities that are exchanging information to use the directory to discover the security credentials of the other entity that is serving as the recipient of the information or with whom the entity is exchanging data. So those were the functional characteristics or the expected functionality that would be supported by this entity level provider directories.

The next slide is sort of the recommendations around the content of the entity level provider directories. So, the information that we thought would be included would be primarily limited to key information that will support the functionality and the discoverability that I mentioned in the previous slide. So it will be limited to information such as the entity demographics, if you will, and identification information – so their name, address and other familiar names and human level contact, those types of basic demographic elements; the information about the exchange services, so the relevant domains and Website locations, URL's, the protocols and standards that are supported by the entity. And with respect to the other information, we identified two options – include a pointer in the directory to the entities information, which was the one that was recommended, rather than including a full roster of information in the directory about the entity itself. And then a general inbox location when applicable so that the entity can receive, whether it's a pick up or drop off location, receive or make information available.

And then with respect to security, again, basic information about the security credentials, their type and location of those for authentication purposes. So, all these are the content elements that support the functionality.

Then in the next slide is a recommendation regarding operational requirements and business model. Here what we discussed was to what extent we can look at the model that would be centralized versus federated versus a mix, and the recommendation was to develop an Internet-like model, nationally coordinated, and in a federated approach model in which there would be certified registrars, entities that are certified to register or to receive the application and process and accept the application of entities that would want to be listed in these entity level provider directories.

There will be national guidelines that these registrars will have to follow in order to accept and validate and process an application. There will be register reciprocity, and the requirement through a publication of the information into a national registry system, so that entities would not have to register. They have businesses in different general register jurisdictions, they would not have to register with each of the different registers but just one registration will be sufficient.

Then the ELTD's will be expected to be maintained and cross referenced throughout the system, sort of in a similar way to the directory names service, DNS, in the Internet. And we have …impossible roles. We've expanded that in the policy recommendation but some potential policy roles of the federal government. Certainly the establishment of standardization and harmonization on a national level of this

requirement, some agencies themselves could serve as registrars, for example, Medicare, CMS, the VA. And then build on existing national federal tools, for example, NPPES, the National Payer and Provider Numeration System, PECOS registration system for providers in the Medicare program and others.

Now, with respect to the policy questions and policy recommendations, we look at these questions that I think Micky mentioned in his introductions. Which business models should the government promote? What are the potential government roles and levers? Because truly, in order to push forward with this fulfillment of the requirement of establishing provider directories, there needs to be a very strong encouragement using national levers.

What is the appropriate level of …of the policy recommendations and avoiding any coalition and stepping into the role of the Standards Committee? We walk very carefully that line. And what is critical and necessary to meet this goal? What are the minimum basic and initial steps and principles?

So we put this framework for understanding the policy options. I'm not going to go into great detail of those in the interest of time, but we did consider different approaches with respect to the infrastructure, the maintenance of the data, the quality and accuracy of the data, which is instrumental in implementing this electronic provider directory. Standards on interoperability, one of the key issues today is the fact that even though we have many provider directories, there is little interoperability between them across organizations. And then the governance and participation, those were the four major areas where we look at policy options.

So let me get into the recommendations of the policy options and then we can open it for some questions. The first recommendation is very directly pointed to the Health IT Standards Committee. The recommendation is the Health IT Standards Committee should be directed to identify the technology, the vocabulary and the content standards that will create entity level provider directory within the policy framework that we laid out, multiple registers and then a single national or nationwide registry system. So some of the characteristics are listed in this slide. There will be a single, nationwide registry that would need to be able to be accessible by EHR systems and that will be fed from the different registrars across the nation. And there's a few other pointers there, acquisition of a security credentials and discoverability of those credentials using the ELPD must be included in the technical approach. Again, not that the provider directory itself will be the administration tool for credentials, but serve more as a pointer for discoverability of those credentials.

The technical approach must also include a process or certification of the ELPD functionality, in EHRs and accreditation of registers. So the expectation that there will be some certification criteria that would need to be put in place for ELPDs.

Then recognizing …question may still be unanswered, the Standards Committee certainly should work very closely with the policy committees Information Exchange Workgroup and the provider directory task force in defining and clarifying any question about the policy direction. So that's the first recommendation. Let me go very quickly through the other two recommendations.

The second recommendation is related to the federal government's role and the expectation that the federal government should use the strongest available levers to establish and to require the participation in this entity level provider directory. So if you point to that recommendation, the registration on ELPD's and use of ELPD's should be considered to be incorporated into the meaningful use stages II and III, and in the NHIN participation requirements the meaningful use workgroup should work jointly with the Information Exchange Workgroup to determine what's the best approach for incorporating this recommendation on the meaningful use stage II and III. And then certainly the governance and participation and ELPD's should be included as part of the NHIN conditions of trust and interoperability that are currently in place and used as a lever to establish the NHIN governance. Or make sure that the NHIN governance includes governance related to ELPD's.

So requiring the ELPD registration for participation in an exchange and director, a couple of examples of some of the levers that can be used. And creating an accreditation process for the registers within the context of other similar accreditation processes.

We listed a few discussion points, but let me just jump into the last recommendation and I'll turn it back to our chair here. So the third recommendation relates to how state level HIE's and other programs can be used as levers as well for the adoption of this provider directory. So state level HIE and Beacon programs should be required to enable the use of a national registry in addressing their constituents provider directory needs. This is something we heard quite loudly yesterday, on Monday, during the session, the panel from Health Information Exchange representatives, that clearly provider directories is one of those key elements that needs to be in place in order for this HIE to be functional. So …consider requiring conformance with the ELPD standards that the Standards Committee would recommend and technical guidance in the implementation of health information exchanges, and encourage a state level HIE program grantees to become accredited registers as a vehicle to ensure that there is engagement and participation and registration of all the information exchange participants in these provided directories. And also to working in partnership with other grantees to create multi-state and regional registers where feasible whenever a particular single state HIE chooses to partner with others and create a much larger regional register.

So those were the three policy recommendations. Let me jump in to close on some of the directions we're taking initially on the discussions of individual level provider directories, which just started a few days ago. So in the slide 19, some of the assumptions on framework, we're going to be primarily looking at using the same type of approach that we use for the development of the recommendations on the entity level provider directory to develop the individual level provider directory. Although of course the level of complexity and identification of use cases and applications is going to be a little different.

We expect that the scope will be national level and there's not expectation that there will be a rigid conformance to it. States are currently implementing individual level provider directories in different ways and we need to make sure that these recommendations are developed fairly rapidly so that some of the guidance can be issued very quickly through states that are moving into full gear of implementation of this individual level provider directories in their HIE's. As I mentioned, we will be using pretty much the same approach as we used in the development of the entity level provider directories, which is listed in slide 20.

We expect in terms of timeline from slide 21 that we will be developing these recommendations during the remaining of this month of January, basically, and then presenting the recommendations to the Policy Committee in early February for their consideration and endorsement.

In the materials we provided, a couple of important things. One is a terminology or glossary, one of the first things we have to develop as we were engaged in the discussion within the workgroup and the task force was to make sure that everybody was using the same term in the same way. So we created a terminology glossary of key terms, basically, that we hope will be helpful in guiding some of the work that the Standards Committee will be doing. And then we also provided, in the second appendix, a series of, well, in Appendix II we provided a list of the high level principles that we're considering in developing this policy recommendation. The principles come from the nationwide framework and a few other national resources, and they're very closely coordinated again with the Security & Privacy tiger team and their recommendations related to security and privacy, particularly …certificates.

And then the last appendix is a series of use cases in which we documented in more detail how this provider directory, the entity provider directory specifically, would be used and fulfill the needs of different users. So with that I'll turn it back to Jonathan. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Walter. That was just a tour de force. We greatly appreciate the task force work. There are moments where you sort of get a premonition of the future and I felt that as you were describing.

Let me just ask, as we move towards the closing comments on this session, if Micky Tripathi, if there's anything that you want to add in at this juncture and then we'll go back to John Halamka.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
No, thank you. I thought Walter did a terrific job and (break in audio)

Jonathan Perlin – Hospital Corporation of America – CMO & President
Micky, I think we lost you. Okay, we'll go back to John Halamka. Any closing framing that you'd like to offer, John?

John Halamka – Harvard Medical School – Chief Information Officer
My guess is is that he had the power outage I was trying to avoid. Anyway, so the question I think now that we've had this wonderful discussion from Micky and Walter, is how does the Standards Committee organize to begin thinking about the standards that are necessary for such things as add, change, delete and query of an enterprise level provider directory. I mean, it seems to me it is less about the schemas about the directory and more about how does in an ecosystem of EHR's and PHR's and various repository, those direct kinds of interactions that need to be able to interact within a directory, what do we do and how do we ensure for our 56 different HIE's that although they may have their individual entity directory, might there be a common mechanism of interacting among them. And so a question I think that I would just raise for a brief discussion, and we can certainly take this offline, Jonathan, is that something that's a part of clinical operations or do we form a new workgroup to dive into the questions of directory structures?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thanks, John. I think that is a very good question, because part of this deals with standards, really. And the good thing is there are a number of standards already out there, including some of the HITSP standards, HITSP T64, for example, some of the ISO standards referenced in HITSP's work, so there is a number of standard IHE provider directory profile, so standards we probably have. And initially one thought was that the work with respect to standards could be taken by the security and privacy workgroup as an extension, if you will, of some of the security and privacy recommendations, particularly linked to what I think will be mentioned a little bit later by Dixie related to the digital certificate recommendations. So I think the security and privacy workgroup might be one place where the standards part could be handled.

I think the other part is really the process, technical process that you mentioned of registration, validation and incorporation into the provider directories and then the query and exchange of data from and to the provider directories. I think that is a question as to whether it's part of the security and privacy workgroup that we have today is part of the clinical operations workgroup or some other group, I'm not sure about that yet.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Walter. I think that discussion teed up a lot of touch points. Certainly, I want to make sure we don't get ahead of our colleagues at ONC and work together in engineering exactly how each of those touch points should be addressed. Jodi Daniel, I saw your card go up.

Jodi Daniel – ONC – Director Office of Policy & Research
Judy and I were actually just having a sidebar on the question you asked, John. I think looking at some of the recommendations here as well and the needs for the Standards of Committee to look at them as well as some of the issues that Farzad and David keyed up for some of the priorities for this year going forward, really focusing on exchange and the transport of data from transitions of care, for consumers, etc., we may want to think about them. We can talk with John and John about it, but would be interested in …may want to think about a workgroup that can focus on those issues and these issues. So it seems as though that might be a worthwhile discussion and something we might be able to consider.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I was thinking this morning exactly that question. Part of the opportunity that we might have or consider at least is that the Security & Privacy Workgroup could be expanded to include security, privacy and infrastructure aspect of it, because this is truly part of an infrastructure element of information exchange. So it could be part of that or it could be a separate workgroup. Anyway, it's something that could be considered as an option.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Does anyone else want to get on the table of this topic before we take a short break?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Walter, it seems to me, I missed a tiny bit of your presentation, I had to step aside, but from what I saw, terrific amount of content there. It seems to me that the majority or at least a substantial percentage of any entity's contacts and eventually a provider's direct individual contacts will already be known because they fit into the common business patterns that you normally use. Just like most of us know the email addresses that we need to know to get our days work done. So it seems to me that the real advance here or the real substance of this is really on the identity proofing aspects of who gets to be included in all this and then on the certificate exchange aspects to manage the PKI infrastructure. Is that a correct set of assumptions or implication for what you guys are doing?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, I think those are the two, I would add probably the third one, which is discoverability of information exchange capabilities. Those were the three things that we thought are the primary benefits and functionality capabilities that provider directories will fulfill, yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Then I would urge you to be sure to pay close attention when you move to the provider specific or the individual directories to the conversations on the learning experience that went through in the Direct Connection Project where we wrestled with these issues for months and came up with an approach that is at least a placeholder for something that brings together a lot of different requirements. So I'm not quite sure who's on your committee that overlaps with that work, but you should be sure to at least sample it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thanks, David. I think that will be what standards committees workgroup that is going to focus on this will need to make sure to consider. The Policy Committee will continue to work on the recommendations now on the individual level provider directory and then have ongoing discussions with appropriate standards workgroup, but yes, I think the standards committee workgroup that will focus on this will need to make sure to look into some of the NHIN direct experience that you mentioned.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let me turn back to John Halamka for any closing comments on this section. I'm sorry, Wes, did you want to weigh in? Wes, you're breaking up. I don't know if you're on a speakerphone.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I just wanted to ask a quick question. As I understand it, it is a recommendation to create a government sponsored director, a government provided directory, is that right?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, it's a recommendation to create a national registry system using government levers. I'm not sure…recommendation for the government to create it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
But the operational word is singular, a single directory system rather than a set of principles by which people might build directory systems, is that right?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, was any estimate made of the cost of doing that?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
No, we didn't discuss any, the issue of cost of establishing something like this. No, I don't think we got into the details of that part.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's obviously vague in its outline, but we ought to, I think, be able to get to some order of magnitude, anyway. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Wonderful discussion, and as we said, this is an absolute prerequisite for enabling the kind of directed exchanges that we would like to have in a standardized fashion and especially across state type interactions using common directory approaches. So I think Jodi Daniel stated it well that we're going to have to organize ourselves to address these many issues, because there are many touch points, some of which are operational and some of which are security. We certainly want to leverage all the other work that has gone before us in the Direct Project, in HITSP, in IHE and in other places.

So with that, Jonathan, I turn it back to you and I think is there a 45 minute lunch break planned?

Jonathan Perlin – Hospital Corporation of America – CMO & President
I don't think it's 45 minutes. I think it's 38, if my math is correct. It's 12:22 in Washington. Let's reconvene at 1:00 pm EST sharp and thank, everybody, for a terrific engagement this morning.

LUNCH BREAK

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, everybody, for a great discussion this morning; reconvening very promptly. For those of you on line and for those of us who are here in Washington and been with some of the folks who are at the implementation workgroup hearings, there's just a palpable energy that really carries forward from the last couple of days. And that energy is the mix of excitement about the future and optimism and commitment, but also very clear articulation of the challenges, the realities of the complexity and the unanswered questions of the work ahead. I wanted to recognize both Judy Murphy and Liz Johnson for their terrific leadership at the Office of National Coordinator for putting this hearing together. They really brought forth so much rich information.

And this information is, of course, brand new and I think it's going to take a little bit of time to process. So in today's discussion it's really not necessarily directed towards recommendation, but really to report. And we look forward to hearing the report and then ask committee members to think about the questions that would allow us to really process the comments with a framing of premature for recommendations, but really making sure we get clarity about the messages. So with that, let me turn to Judy Murphy and Liz Johnson with great appreciation.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Thank you, Jonathan. So this is Judy Murphy. What we'll do is talk a little bit about the mechanics of the hearing itself as a start and give you a very brief look at what we heard, and then talk about our next steps, because not only do we have to synthesize our thought process in terms of the recommendations, we actually have to synthesize our thought process about what we all heard as well and correlating everything. You'll understand why in a minute when I show you the plethora of people actually that we had testify.

So a thank you, first of all, to the Implementation Workgroup members who are listed on the slide. They did help give us direction in terms of not just the testifiers, but also in terms of the questions that we should be asking and the way we should organize the panels.

Someone who is not listed on this slide but who also needs recognition is Judy Sparrow. As always, Judy helped us pull everything together, sent all the invitations, got all the RSVP's, coordinated everybody getting the official invites and the questions and those kinds of things. And let's just suffice it to say that this was happening over the holidays, so the office of no Christmas rides again.

In terms of the panels, we organized around five different panels. There were two on Monday and three on Tuesday. The two on Monday looked at regional extension centers and EHR certification process. The implementation support, looking at health information exchange started us out yesterday. And then we had two panels of eligible providers talking about their experiences as early adopters and two panels of eligible hospitals talking about their experience as early adopters seeking attestation.

The panelist questions were essentially around these four concepts. They were tweaked a little bit based on whether you were a health exchange or an early adopter seeking attestation. But we asked them to identify the challenges, barriers and successes, to outline the implementation approaches and methodologies that worked and didn't work, including their real world user stories and examples. We asked them to discuss their outcomes and results, including any surprises or unexpected outcomes and how they were addressed. Lastly, to talk about their experience using the ONC and CNS communications regarding the meaningful use criteria, the standard specifications and the measurement criteria.

Again, the first panel, which was on Regional Extension Centers, I'm not going to read the names, but basically we had two Regional Extension Centers testifying. Then we had two users of Regional Extension Centers testifying. Then we did have somebody from the Office of the National Coordinator as well, who served really in a role of reactor as well as providing information.

We followed a similar process with certification. We had CCHIT testifying in terms of a provider of certification. Then we had three folks testifying in terms of their experiences as they were achieving certification. Then we also, again, had somebody from the Office of the National Coordinator speaking to that process. For the health information exchange, followed again a similar process. We did have two people from an exchange and then we had a third person who was the user of an exchange. Then we had somebody from the Office of the National Coordinator.

I mentioned for early adopters in the eligible provider space we had two different panels. You can see by the long list of names that it was important to divide that up into two. We did a very good job, I thought, of making sure we had different kinds of vendor representation, different geographies, as well as large and small providers. We did have the single physician practice represented as well as the large physician practice. We were able to get reaction from somebody from CMS, Rob Anthony, as well as somebody from the ONC.

Then our last panel, again, was divided into two. This was the eligible hospital space. Again, we were looking at variable geographies, variable vendors, large and small. Mostly everybody was very serious about either attested in 2011 or they were looking at attesting in 2011 and for some reason or another had chosen to wait until 2012 and were talking about their experiences there. In this space, we were able to have reaction, again, from Rob Anthony from CMS.

Okay, I'm going to turn it over to Liz to talk a bit about what we heard.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

As we begin to talk about what we heard, we want to predicate it with something that Jonathan sort of opened us up with, which is we heard significant passion and enthusiasm about the process. This is something they want to happen, they believe in, they have concerns, but please hear us, this room really

was full of people that care about quality and want this to work. We felt like they were coming from a very objective set of views and provided us with extraordinarily valuable information.

As Judy indicated earlier, we're really going to just give you themes today. We have a summary to go through that will go on and on for many, many pages and slides. We'll be back to you in an upcoming month with much more detail, but we want you to hear the general themes that we heard from each one of those panels.

First, we'll talk about the Regional Extension Centers. It was an interesting panel. We really got mixed reviews on the value of the Regional Extension Centers, and I think that's telling to us that there were two things that we saw there. One was those who utilize the services and were very satisfied and those that utilized or couldn't find the services that were not satisfied. As we began to delve into that, we found part of the reason for that, which was there was significant variation in the way that Regional Extension Centers work region to region. That is in terms of the cost, the customers and the definition of the business model—very different. In fact, we determined that there were at least four different models, and we'll come back to you on that, as to the way a Regional Extension Center might work. So, I think that is going to lead to variation in satisfaction and services and we're going to need to add more clarity, not only to this committee, but back to ONC, on what we do with that information. It was also very clear that what the best practice was, what is the right way to run a Regional Extension Center and what should our customers expect is unclear.

The next thing we moved on to was our certification panel. One of the things that we found to be absolutely consistent and very costive was that once you get into the certifying body, that process is working very well. The certification body in this did not come from our … certification body, but the users, the vendors, of those bodies found them to be very thorough, to be very responsive. They're doing a good job.

Now, when we got into the certification rule themselves, this would be more from the vendor perspective, we found that there were a number of challenges that they're dealing with. A lot of those particularly related back to both the purchasing process related to determining what vendor product you buy as well as the implementation challenges. Let me be more specific. There is a great deal of interested and wanting of further definitions around modular certification—not what is it, but what do I buy and what do I use around modular—versus buying complete. We'll give you more details. Let me just—because otherwise it would make no sense to you. The question becomes if a certified vendor has a list of products that all the products together equal the … certification, do I have to buy them all? Can I buy a mix and match combination? There's much more detail to add there, but it was clear to us that all the providers as well as the vendors were struggling with that aspect.

The second thing is—and that really leads to—what is a complete EHR and how do the providers and the vendors then work with—first the vendors with their customers, and then providers to meet the need of attestation. Make sure they're meeting that definition so that we can mix and match products to get to a complete solution. It was a very empowered discussion—shall we say?—with much emotion. Again, I think you need to hear that what they want to do is the right thing. They want us to make it easier and more clear on what to do and then they will do it. I think that is really good news for us.

Then we had another lively discussion with the health information exchanges. We talked about it earlier, so we won't say this and we heard from you that you already know this and we know it as a group is they want interoperability specifications. They want them now and they want them to be clear and concise. It was very clear to all of the members of the workgroup and those others participating in this that both as a … and value proposition related to health information exchange is unclear. How are we going to keep these things going when the money goes away? What is the real value? We all have added to that conversation this morning. The real conflict between private and public, between local and state and national was out there. They want to do the right things. They need more clarity from us. That led to varying initiatives or unsure when, where and how to sign up and what they should sign up for. Interesting conversation, much more to come.

The next group that we heard was really—the theme we heard, I should say, actually—is really around timing issues. There was a consistent theme that with the meaningful use criteria finalized in July of 2010, there were some expected, I presume, outcomes of that, but they are now dealing with that. The first one was we are still getting late vendor software changes. Upgrades are still coming. Patches are still coming. So, as we get ready to do attestation and go through that process and meet the intent of the rules of meaningful use, our software is still in movement. Late certification: Obviously, one follows the other. If the products are still coming out, then certification of the product has to follow that. So, there's a timing issue. Then, final, late delivery of the upgrades. So, it is clear that the meaningful use criteria isn't—not that they didn't understand what needed to be done that I think we've accomplished, it is getting the vendor product … ready certified and available for our eligible providers and providers to use.

The next … was around communication. Again, a very enlivened and very emotional kind of a thing. I use the word emotional because I think they want this work, so they get very passionate about it. We saw great passion. In fact, as much as 11, 12 hours of testimony might sound like you couldn't get through that, we could get through it because they were moving us through it with great enthusiasm. They felt like that they want prompt responses from ONC and CMS. They acknowledged that the FAQs are out there, but they also acknowledge that sometimes FAQs are confusing. One may seem to be differing from the last answer to the same question. They want the help desk to be rapid respondents to their questions and very clear and concise.

They also want consolidated documentation. I think that this is an area where we need to work together with CMS and ONC. It needs to be reliable. It needs to be clear. It needs to be complete. And it needs to be in one place, one source of truth. We all have been out there ourselves and worked through the process of finding answers. The answers are there, but it is not an easy process and that's what we heard from the persons that—through all the panels—they are looking. They have found significant amount of information, not easy to navigate.

Another clear theme was the quality measures are difficult. They're difficult to understand and certainly they are also, there's potential that we are reporting on several different aspects of the same quality measures to several different agencies with slightly different requirements, and can we bring that together. And I'm looking at Janet because I know she's going to solve that for us. We really did hear that. Again, the underlying emphasis was it's the right stuff, we were measuring it for the right reasons. We do want to get to population health, we do want to make a difference in the way we deliver care, so we want some more input on the quality measures and what's coming. But the quality measures are a very difficult part of the standards of general meaningful use.

We really heard a variety of implementation stories and we'll share those back with you in more detail later. People are on all different places. As Judy said, some have chosen to slow down, they want to do this right, they don't feel like they can get every piece of it right. They're dealing with public surveillance, they're dealing with immunizations, they're dealing with things that are not clear pieces and parts to – HIE and so on. And so I think, again, we will come back to you with more cases.

We've talked about actually testing that against use cases so we can bring you very clear and crisp information that you can understand. And this was one that was not a surprise, but it was very telling in that they want a long-term meaningful use roadmap. Let me explain to you what they want. They want to know what is coming in three to five years. They understand that the level of absolute detail may not be able to be there, but they're already both our vendors, our implementation groups, our implementers are all trying to determine for a roadmap where will we be going so we can start to get ready, so the things that we do now will fit into a roadmap later. So it's clear that although we aren't going to be to give them every detail, they want to know the general direction. Let me give you a specific example.

If we believe that at the end of the day we're going to require 95% of all orders to be done in CPOE, not just medication orders, all orders, tell us that now, even if it's three to five years out so we can start to plan for it. And so, again, I think they understand that this is an evolving world, that we want to be responsive, that everything will not be complete. They do want to understand general direction – what

does interoperability look like, how should we be using our HIE's, what's the long-term plan for Rx and so on.

So again, very, very synthesized set of information we're providing back to you. We will ask in a little bit other workgroup members to add to it, but I think we found it to be very invigorating. I think that they want simple, clarified answers; answers to where we're going from here.

Before we get to next steps, we will take the group back and those I recognize that are in the room may not have our slides yet, but we went back to the ten recommendations that we brought you the first time the Implementation Workgroup met. Things like keeping it simple; design it for the little guy, etc. You remember those? They were very, very powerful. Well, we are going to be working with our chairs and with others on is can we take not what we've learned as a general standards group, but as an implementation workgroup and take these principles and apply them to what we heard in that hearing? Are we keeping it simple? Are we really making it something that they can work with? Have we taken costs into consideration? Are we doing the right thing to support our implementers? And I think it will be a piece of work that we do as a work group that will come back to the Standards Committee and make it even more meaningful for us going forward.

With that, I'll turn it back to Judy for our next steps.

Judy Murphy – Aurora Healthcare – Vice President of Applications
So we controlled ourselves from giving ourselves a grade point score on these ten and we kind of stopped after number one, because the word that we heard most frequently over the last two days was complex, so we kind of held back. But I think it's going to be important to revisit these recommendations and say we thought they were valid when we started this journey; are they still valid? And if so, how are we doing? And if we're not doing so good, how do we correct it? And then of course there's some that maybe we really thought were important in the beginning that we're now not going to say are as important as we thought originally. But we thought it helpful, I think, as an exercise to go back and do this, so that's something on our to-do list.

So the remainder of the items on our to-do list really look at summarizing all of the hearing findings, putting them in a way that we can feel like we've organized them appropriately and we have, again, a start on that from the first couple of slides that we just showed you today; comparing them, again, with those top ten recommendations. Formulating additional recommendations as a result of where we are. and I want to emphasize something that Liz said here. Almost to the person, we got the can-do attitude. I mean, these were people that were really digging in and trying to do the right thing, and trying to understand everything. And it was in that journey that we heard things like the quality measures and how difficult they are. And in fact, Rob spoke up at that point and said, "Well, we've got this one-page criteria or these fact sheets around all the meaningful use criteria." And so then the next question was, "Well, do we have that for the quality measures?" and of course the answer was no. And what happens with the quality measures, I happen to know myself, you're taken from one Website to another Website to another Website and you end up on a 487 page HITSP document.

Now maybe that's required, but maybe we should also be able to explain that in a way to people that have maybe left with a can-do attitude. And what I mean by that is these are the folks that have been listening and following, that's how they were selected to be some of our panelists, and oftentimes they were saying things like, "Hey, we're really trying to do this. What about the average guy? What about the common guy?" And so that theme kind of came up through the two days, too. So again, that goes back to what can we do to make this really understandable for everybody.

At any rate, we need to obviously discuss that then with the John's, in terms of what our next steps should be and how we should take this synthesized list of recommendations. We do want to discuss this also with the Health Information Technology Policy Committee, the Adoption & Certification Workgroup. Mark Probst and Paul Egerman were part of the hearing process since there was some overlap with the Adoption & Certification Workgroup of the Policy Committee, and so we certainly want to discuss which

things should they take versus which things we think we should take, and then create an overall action plan and come back to you all.

So with that, I think what we'd like to do, there are several people in the room here who may want to comment who were at the hearings. So if the chair doesn't mind, we could open it up to them first and then open it up to general questions?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. Love to hear from those members of the Implementation Workgroup who were there.

W
They know I have a lot to say, but they've done such a good job. I appreciated the two days of testimony, but I heard a lot of things that I've heard many, many, many times already expressed throughout the committees and the workgroups that we've already had. And one thing, I'm not going to pick all of them to say that I've heard before, but one thing that I would like to emphasize is the communications issue and the one-stop to get some information. Right now my primary source of information is John Halamka's blog. If he did not put together some information in a big picture view, I don't know what I would do as a committee member to understand some of the bigger picture items. So what I'd like to just reinforce is the need for some big picture discussion of where this is all going so that the average person who has to implement it has some idea of what the end game is, because it is a good goal, it is an awesome goal. It was one that pockets of people are dedicated to for the pocket reasons – quality people want quality. There's different directions, but there's a bigger picture and accountable care organizations is one that's big mystery that's not yet solved. And I think there's some knowledge of those big picture goals that could be shared more globally to more people than just us so that we can prepare the country for where we're going. That's what I want to put in a plug for. Thanks.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I'm not a member of the Implementation Workgroup, but I did attend the two day hearing. As it was mentioned, it was invaluable. I think we heard a lot of frank and open discussion and points about some of the issues.

I wanted to highlight two issues; one that has been mentioned already, which is a lot more coordination between the different programs. We heard about the 50+ regional extension centers and how each one is doing things a little bit differently, but there is a lot of communication happening. We also heard about the HIE grantees and how they're communicating, but we heard a need to have a lot more dialogue between them, between the regional extension centers and the HIE's and the other grantees in terms of finding some of the best practices, some of the ways in which organizations are doing things that are valuable. So that cross-coordination between programs, I think, was one of the points I thought was very valuable.

The other one was something I mentioned earlier today, which is this concept of care coordination and the concept of continuity of care and how ultimately one of the most important goals across the board is to ensure that when patients come to one provider and then go to the next, or referred to one and another, or exchanges happen between two different entities that all of it is really in pursuit and improving care coordination. And I think measures to help evaluate how we are improving in that care coordination is something that it's going to be necessary.

John
I think you guys did a great job. I had about 15 pages of notes and you guys summarized it in one slide. I just want to emphasize, this is based a little bit on the KISS or Keep It Simple, Stupid, and also on I saw some competitiveness. I know when we talked about directs, that was in purpose of ONC to have four different models and how to compare them to come up with the right model. There's a whole bunch of models on HIE's. I mentioned yesterday that I worked with a number of states and each one of them is different and it's going to be very difficult for me as a provider to be able to do all these different models.

Then also I heard some vendor things that I didn't like to hear. The vendors are, and I used to be vendor, so I can say something like this, a little greedy sometimes on what they were charging. And I mentioned that one state was going to charge us, which Marc might not, don't know if you know this one, Marc, but it's not his state, he's very fair about it, but another state was going to charge each nursing home $2,000 a month to be part of their, and we happen to have 20 nursing homes in that state. And I said, "This is outrageous for us to be able to participate."

And then there's something on certification, there was a concern about if you get it certified for stage I, would that certification be good for stage II and stage III or would I have to go through and do it all over again? And then there was one about insurance companies trying to take control. So my end remark is I think we're at the time when we can say we've had enough models and all that and they want some pure direction, and not to keep experimenting. Tell me what I'm supposed to do so I can go do it.

Judy Murphy – Aurora Healthcare – Vice President of Applications
I will dovetail on to that comment. I know my first comment at the meeting today was just tell me what we have to do. And I will say that was the theme. However, people I think as they were testifying were balancing this we need to innovate and try different things, but I think they were also saying, "Been there, done that, now tell me what I have to do" kind of thing. So we can't continue to innovative forever and let's lock and load the model.

Another theme was a bad standard is better than no standard at all. We heard that several times.

Anybody on the phone, Cris Ross, are you on the phone and want to make a comment? He was going to try to dial in.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I was listening on the phone to most of the testimony and I think you guys captured it really well. One thing that struck me was the sort of huge disparity between the groups who think they have this under control and the groups who feel overwhelmed by it. There really is a tremendous range out there and we shouldn't just be listening to the ones who have it under control.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Thank you.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That's a great comment. And we really did hear kind of the dichotomy that was going on all over the place. Again, I think one of the comments that Judy or someone made earlier is we were really, actually one of the panelists may have made the comment, that we were really talking to probably at best the top 25%. So we were talking to people that are early adopters and yet we saw concern. So if we see concern at that level, then we should anticipate that people that are not as ready, there is far greater concern. So we need to delve into that and then just stay in not just from the very early innovators, but from those who are quickly trying to catch up – what are you facing and how can we help you?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
The other thing that came up a number of times, I think you covered it, but I had to duck out for a second, so I didn't see all your slides, was the urgent request that all of the requirements that come from HHS and its branches be synchronized so that they don't have to solve these problems over and over again, quality measure reporting, etc.

Judy Murphy – Aurora Healthcare – Vice President of Applications
I think that went back to that roadmap idea. If I know what the end game is and then you tell me I have to get this far now and then here's the next milestone, I at least know where the end game is going to be.

With that, I'm going to turn it back over to Jonathan.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much for a very thoughtful, provocative and important summary of the experiences. In the next couple of minutes, are there any immediate reactions or comments or inputs from committee members that you'd like to use to sort of seize the ground for a thoughtful review over the next month or so?

Martin Harris – Cleveland Clinic – Chief Information Officer
This is really for Judy or Liz. As I looked at your list, and it really was quite comprehensive, I didn't see a category which I call meeting the spirit of the regulation, but not the letter of the regulation, and I'm beginning to see it both here at the Cleveland Clinic in my role in terms of the broader state implementation. So the scenario is this, we're well down the road, we have scorecards right down to the physician level. We're starting to see what I would call workflow challenges that are inconsistent between the spirit of what we're trying to accomplish and the actual measures. So the classic example is in pain management or in some of the sub surgical specialties, where in almost every visit they're going to be using a narcotic analgesic, and in the state of Ohio you are required to print that out and have the patients physically deliver that to be filled. So from a workflow point of view, they are actually doing everything that's required; they're using the formulary model, but they are not going to be splitting their workflow so that if it's not a narcotic, they would actually for one patient send it electronically, which then gets you to the e-prescription writing component. And then for their narcotic printed out, they are going to print it out. So on a scorecard basis, they're not going to pass, but from a spirit point of view they've actually accomplished the greater goal here, which is using the formulary to make sure that they're delivering the best value to the patient as they care for them.

So my question was, one, have you heard of more examples like that? And the second is, is there a process, and I'm imagining these scenarios will come up more and more as we pass through the year, is there going to be a process to try and handle that conflict as we go forward?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Excellent. It's as if you were sitting in the room with us. We did hear that. In fact, we got into sort of a positioning where we were asking clearly is this about the standard, is this about the process, is this about the vendor or are you doing this because you're doing it to meet meaningful use? And much as you just illustrated, and I'll give you another illustration, we are seeing a mixed response to that. What I mean by that is the discharge process.

We had persons that if you look at the checklist, as you said, and they follow the exact letter of what is needed to certify, they would have to do things in their practices or in their hospitals that are nonsensical from process perspective. So they have chosen to continue their current process, recognizing they don't meet the specifics of the law, but they meet the spirit. So I think as Judy and I and the other workgroup members taught, we're going to have to eliminate where are those disconnects and what can we do about it? Because what we heard over and over is, we believe the intent was that you are truly trying to get us to use processes that improve the quality of care and provide our patients the right information and our providers the right information to do a better job, not to disrupt that. And what has been a result of trying to instate in a very pure way meaningful use measures is additional workflows, additional steps and extra things going on that are effecting our efficiency and not necessarily improving our quality. So that challenge was put to us and I think you did a very good job of articulating it. Now I think our job is to gather further examples of it and use cases to then come back and say, "What can we do about it?"

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's very much in the spirit of today's discussion report, and I'd recommend, again, just a terrific set of activities to bring the insights of how it's playing across the country among really thousands, if not hundreds of thousands of individuals and institutions that are highly motivated and trying to make sense of the complexity.

Just making sure that workgroup and the broader committee, the ONC capture all of the areas. If others have thoughts about what they heard, reflections on that, get those to the co-chairs, Judy Murphy and Liz Johnson as well as Judy Sparrow so that it enters part of the public discussion as …requires, that would be terrific. Over the next month I know that the larger committee and the workgroup and the ONC will be

putting heads together to think about how this feeds into the go-forward agenda, very much in the spirit of the good guidance Cris Ross gave us this morning, which is how does the entire process sort of self-rectify in terms of learning and improving and supporting the desired ends.

So terrific work. Again, thanks to all who participated, all who presented at the hearings and together members of the workgroup.

Well, there's been a theme today in terms of continuity of activity. I mentioned at the outset that devices are located across all environments. We're reminded by Dr. Ondra and others that ecosystem extends right to the patient. In fact, the more we think of the point of service not as a place, but in fact the patient, I think that the better the operating paradigm becomes. But in order to really move from metaphor to practice, there is a sense of requirements and that relate to device standards. And we appreciate Jamie Ferguson's workgroup leadership and attention to those device standards. Jamie, let me turn it to you. Certainly, John Halamka, you want to join in. Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much for the introduction. I think that this is probably going to be the briefest presentation and possibly, well, I can't turn back the clock, but I can contribute to getting us back on time, because if I sense the last committee meeting due to the holiday schedule and so forth, we have not had a workgroup meeting. We have two of them planned within the next month to discuss this issue and to plan our hearing on Device Interoperability, so I'll just recap what I think you've heard before. There have been some discussions among committee members on what we need to consider in the workgroup, but we haven't actually had workgroup meetings.

In general, the overriding purpose of the hearing is really to identify barriers and enablers for device interoperability and we're currently considering planning a hearing around three main themes. One is the interoperability requirements for variety of use cases in different care settings. And so that would be in the ambulatory care coordination in terms of inpatient, but also home health and long-term care settings and how device and remote sensor data can be best integrated into the electronic medical record standards in terms of meaningful use from that perspective.

We also planned a second theme around security and device security, and there are a variety of different issues there that, again, are different for the different use cases and different care settings.

And then finally, I have had some initial discussions recently with the FDA's UDI, the Unique Device Identifier Workgroup. The FDA is planning on conducting rule making activities around the UDI that in terms of timing would be very much in synch with the timing around further rule making, around meaningful use, and so there's a need for some coordination there. And the FDA's unique device identifier is essentially a framework and in some ways conceptually similar to RxNorm as a standard in that it contains other parts of standards, such as device nomenclature that then we've also discussed in the context of the Vocabulary Workgroup. So the third theme them would be unique identification on devices and the scope of that, and also I think part of the consideration there is the need for coordination with potential for FDA rulemaking that would coincide in time with the meaningful use rules, if there are any, around this area of devices.

So those are our current themes for consideration. I'd love to take more input from the committee members and also encourage folks to participate in our planned workgroup meetings on this subject.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great, Jamie. Thank you very much for thoughtful update on what's coming in the next two meetings. John Halamka, anything you'd like to add?

John Halamka – Harvard Medical School – Chief Information Officer
Just recognize, Jamie's group is working on two important issues – the device issue as he just described. That will become increasingly important as we see more care in the home, which one guesses is going to be part of healthcare reform. But also to make sure that the content expertise of the folks on the Clinical

Operations Workgroup advises the whole S&I Framework activity and their prioritization, because the folks on Jamie's team really do have rich expertise implementing the kinds of standards that Doug and Arien talked about as those initial three priorities for their work. So that will be the next 30 days of activity.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That, I think, the competency you both offer are very consistent with both the opening of today's activities as well as sort of meta message from the Implementation Workgroup hearings. If anyone has any specific input into areas they'd like to expand, please get in touch with Jamie and John, and we'll look forward to more robust discussion about the content of those next two meetings in our next meeting.

So with that, let's turn to the last order of presentation before we get to public comment. I want to thank, as always, Dixie Baker for her terrific leadership, the Privacy & Security Workgroup, and look forward to hearing your update on digital certificate standards.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Today I'm going to be competing with Jamie for the briefest presentation. We don't have a lot to report, but I did want to update you on three activities within the Privacy & Security Workgroup.

The first is that, as members of our committee will recall that at our last meeting the Privacy & Security Workgroup took on an assignment from the Policy Committee to develop recommendations for digital certificates. Of course, digital certificates are basically electronic records in patients of identity. So they're used to authenticate organizations, to authenticate software, servers and also to authenticate individual people.

We have begun work on this assignment and we're focusing that work on what the Privacy & Security tiger team calls "directed exchanges," which are those exchanges of clinical information between provider organizations. So this work is quite complementary to the work that Walter Suarez reported earlier today on enterprise level provider directories, and our work on digital certificates, I'm sure, will maintain synchronization with the recommendations and work that's coming out of the Policy Committee.

The second point I wanted to make is that several members of the workgroup and the committee as a whole are continuing to serve on the Privacy & Security tiger team, that works from the offices of the Policy Committee, and namely David McCallie, Wes Rishel, Carol Diamond and myself. The tiger team right now is completing its recommendations regarding patient matching.

And then the final thing I wanted to tell you is that Steve Findlay and I recently discussed the many demands that he has on his time, and we concluded that he …these demands. It's in the best interest of our workgroup and the committee might better be served by having someone else serve as co-chair. So Walter Suarez was asked to take over this position and I'm very pleased to report that he has accepted and will be my co-chair moving forward.

So, first, I want to thank Steve for his help to this point and also to thank Walter for his willingness to take on these responsibilities. That's it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dixie, we thank you for that and, Walter, thank you for volunteering. Let me just ask, before I make a final couple comments if there's any questions for Dixie, anything that you wanted to tee up, anything else for the good of the order before we move to a public comment period? Okay. Well thanks, all, for this part of the meeting. Let's hear the input from those members of the public who'd like to provide input either here or virtually. I'll turn to Judy Sparrow to facilitate that portion.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. And if anybody in the audience wishes to make a comment, please step to the microphone. If you're on the telephone just press *1 to speak. If you're on your computer, you have to dial 1-877-705-6006. Carol Bickford, you have a comment.

Carol Bickford – American Nurses Association
In relation to the testimony that we just heard about the directory standards and the categorization of the individuals, I want to bring to the attention of that group that there was significant work done by the American Nurses Association who participated in development of the disaster registry, which is an entirely different use and wouldn't be considered for the NPI, perhaps, as the existing architecture for the directory. So please consider both of those options to assure you've got the full spectrum encompassed.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Carol. I don't think we have any comments on the phone, so I'll turn it back to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, then let me actually …two presenters the most brief and simply thank you all very much for all the hard work, all the great input and in advance for all the work ahead. And as we close, I wish you a happy, e-healthy and interoperable New Year. We stand adjourned. Thanks.